Laurence M. Rosen, Esq. (SBN 219683)
THE ROSEN LAW FIRM, P.A.
355 South Grand Avenue, Suite 2450
Los Angeles, CA 90071
Telephone: (213) 785-2610
Facsimile: (213) 226-4684
Email: lrosen@rosenlegal.com

Lead Counsel for Plaintiff

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

VICKY NGUYEN, Individually and on behalf of all others similarly situated, Plaintiff, v. ENDOLOGIX, INC., JOHN MCDERMOTT, and VASEEM MAHBOOB, Defendants.	Case No: 2:17-cv-00017-AB-PLA **SECOND AMENDED CLASS ACTION COMPLAINT[1] FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Hon. André Birotte Jr. **JURY TRIAL DEMANDED**

Lead Plaintiff Vicky Nguyen, ("Plaintiff"), by and through her undersigned attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, her counsel's investigation, which included without limitation: (a) review and analyses of regulatory filings made by Endologix, Inc. ("Endologix" or the "Company"), with

[1] A redlined draft showing the changes between the instant Second Amended Complaint and the First Amended Complaint is attached hereto as Exhibit 1.

the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases, conference calls and media reports issued and disseminated by Endologix; (c) investigative interviews with former employees of Endologix having first-hand knowledge of the Company's operations; (c) consultation with an expert in preclinical and clinical trials and U.S. Food & Drug Administration ("FDA") procedures, FDA regulations and guidelines; (d) review of other publicly available information, including information on the FDA web site, medical journals, analyst reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased or otherwise acquired the publicly traded securities of Endologix between May 5, 2016 and May 18, 2017, both dates inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Endologix is a medical device company that manufactures medical devices used to treat abdominal aortic aneurysms, a serious medical condition that can result in death if the aneurysm is untreated or treated improperly.

3. Endologix's future growth prospects and its primary selling point to investors rested squarely on a device called Nellix. Unlike other devices to manage aneurysms which are based on the principle of repairing the aneurysm, Nellix seals the aneurysm sac. Nellix was touted by Endologix as eliminating the risks and complications posed by traditional aneurysm repair devices: namely endoleaks (i.e.

blood leaking back into the aneurysm sac) and device migrations (i.e. the device moving from its initial placement).

4. Not only would Nellix be the first device of its kind but Endologix intended it to be a "one size fits all device" that could be used to treat every patient anatomy. Nellix's ability to be used to treat patients with even complex anatomies was critical to its commercial appeal. As one JP Morgan analyst stated, "Nellix has demonstrated the potential to address this unmet need [of treating patients with complex anatomies]. In the EVAS Global Registry 35% of patients treated with Nellix had complex anatomies, *including many who would not have been able to be treated endovascularly otherwise*." (emphasis added).[2]

5. Prior to and during the Class Period, Endologix sold Nellix in Europe, where it was approved for use in patients. In fact, by the time the Class Period began Endologix had been selling Nellix in Europe for over three years since February of 2013. By the time the Class Period began Defendants possessed a trove of clinical information based upon on the real-world results of thousands of patients in Europe who used Nellix. All of these European patients' experiences, including complications, adverse events, and doctor complaints were documented in the Company's comprehensive database and were scrupulously analyzed and studied by Defendants.

6. In order to market Nellix in the United States Endologix would need FDA premarket approval. Premarket approval is the most stringent application to the FDA to market a device and requires valid scientific evidence to satisfy the FDA that the device is safe and effective. To that end, Endologix sought and received approval to begin a clinical trial for Nellix which began in January 2014. In May of 2016,

[2] JP Morgan analyst report dated August 6, 2015 "Upgrading to OW; Time Is Finally Right to Play the Nellix Opportunity."

Endologix told investors that it had submitted positive clinical data to the FDA as part of the premarket approval process for Nellix.

7. In addition to the clinical data that Endologix submitted to the FDA from its two clinical studies, which together consisted of less than 500 patients, FDA regulations required that Endologix provide to the FDA all of the data and information from its commercial marketing experience with Nellix in Europe, including all adverse event reports and complaints by doctors and patients in connection with Endologix's PMA application.

8. By August of 2016 Nellix had been used in over 6,000 patients and by November 2016 that number rose to 7,000. Because Endologix could not sell Nellix in the U.S. 6,500 of those 7,000 patients were patients in Europe who received Nellix through the commercial channel in Europe. The experience of these 6,500 patients who were implanted with Nellix, and any reports of adverse events or complaints from these patients were required to be disclosed to the FDA and were relevant to and would be considered by the FDA in determining whether Nellix was safe and could therefore be approved for sale in the U.S. *See* 21 C.F.R. 814.20(b)(8)(ii). Indeed Defendants stated that the patient data from European patients would be provided to the FDA and serve, along with clinical trial data, as the basis for PMA approval.

9. During the Class Period, Defendants flooded investors with rosy results from their clinical findings and repeatedly stated that they were on track to receive FDA approval of Nellix in the U.S. at the end of 2016 or in the early part of 2017. In investor conference calls and press releases Defendants assured investors that everything in the data looked positive and that there was nothing concerning the potential for FDA approval of Nellix and the Company's interactions with the FDA "that's given us heartburn."

10. When asked how Nellix was doing in the "direct channel" in Europe, Defendant Mahboob told investors that it was doing "a fantastic performance."

11. The reality was starkly to the contrary. A confidential witness ("CW1") who is the former head of Aortic Procedure Development at Endologix, personally recruited to work at the Company *specifically* on Nellix *since its inception* by Defendant McDermott (whom he had known personally for thirty years) provides a compelling account of how Defendants were well aware of, indeed consumed with, a serious and unsolvable problem with the Nellix device since the beginning of 2015.

12. By late 2015 the serious problem of Nellix and migration became a consuming issue throughout the Company. The Nellix device would migrate, or move, from its initial placement in the patient, a complication which significantly increased the risk of catastrophic consequences.

13. The Individual Defendants were briefed weekly and at times daily about the increasing number of complaints from doctors in Europe, where Nellix was actively marketed. These complaints and adverse event reports were documented and were stored in the Company's thorough complaint database. By October of 2015 it was clear to Defendants that the device was especially dangerous in patients with a lot of thrombus, or blood clotting. Beginning in November 2015 at the latest, McDermott was urged by senior scientists at the Company to issue field safety notices for physicians using Nellix to take field safety corrective action[3] and to narrow Nellix's indications for use ("IFU") to exclude patients with thrombosis, who Defendants knew were at a high risk for migration, in order to prevent serious

[3] A "Field Safety Corrective Action" is a term defined by the European Commission DG Enterprise and Industry and the FDA as an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions should be notified via a Field Safety Notice. https://www.fda.gov/OHRMS/Dockets/dockets/06d0011/06d-0011-gdl0001-Tab-07.pdf .

adverse events caused by migration. But, notwithstanding the immediate known danger to patients, McDermott simply refused to issue the FSN and narrow the IFU.

14. In January 2016, McDermott personally created and oversaw a "task force" at Endologix to address and solve the problem of migration.

15. McDermott personally approved the Company's presentation on Nellix and migration, which was presented at a non-public symposium attended by insiders in London only two months before the beginning of the Class Period.

16. While Defendants made every effort to correct the migration problem the Company not only was unable to find a solution but also was unable to find a cause. Defendants intentionally hid this from the market. McDermott continued to refuse to issue field safety notices even after reports from European doctors reached a near-crisis level in March 2016, with the Company's closest surgical advisor and earliest user of Nellix in Europe telling the Company that the situation was "urgent."

17. McDermott's refusal to issue the field safety notices and narrow Nellix's IFU put patients' lives at risk and was not only illegal but also immoral. When CW1 and other senior officials at the Company working on Nellix listened to an investor conference call on May 9, 2016 in which Defendants never mentioned the word migration and described "good feedback" on Nellix from doctors in Europe, they were "shocked and disgusted" and left the Company as a result.

18. Defendants' knowledge of the foregoing rendered all of their statements during the Class Period concerning Nellix's excellent prospects for FDA approval and Nellix's fantastic performance in the direct sales channel in Europe materially false and misleading.

19. Nellix could not and would not be approved by the FDA consistent with the timeline Defendants were putting out to investors because the inexplicable and frequent incidences of migration rendered the device unsafe.

20. In November of 2016 when the problem of Nellix and migration finally came to the fore Defendants continued to lie to investors, telling them that the incidences of migration were only discovered during a "recent data cut" in patients "with a lot of thrombus" and that in any event there was an easy fix and that this would not alter Nellix's prospects for FDA approval.

21. It was only then that Defendants issued a field safety notice or "Dear Doctor" letter and revised the IFU for Nellix, narrowing it to exclude patients with thrombosis, despite knowing that field safety notice and the revised IFU were necessary and should have been issued ***one full year prior***.

22. The incidences of migration in the U.S. clinical trial data became painfully obvious to Defendants beginning in January 2015 (a year after the clinical trial began) as one-year post implantation data became available. In fact, the sharp increase in migration between the first and second years of Nellix being implanted in a patient was entirely consistent with Defendants' real-world experience with patient use of Nellix in Europe.

23. The number of patients who received Nellix in Europe far outpaced the number of patients in the U.S. clinical trial given that Nellix had been marketed in Europe since February 2013.

24. On November 16, 2016 (less than two weeks after announcing the narrowed IFU) unable to avoid the inevitable, Defendants revealed to investors that because of the severe problems from migration, the FDA had required Endologix to complete another two years of patient follow-up data on its U.S. clinical trial before it would consider approving Nellix. On this news, Endologix's stock fell $2.02 per share, or over 20.5%, damaging investors.

25. Indeed, the FDA's request for two-year follow-up data was in response to the evidence that Nellix was migrating and endangering patients' lives.

26. Because the FDA requires that all adverse event reports be disclosed in the premarket approval application - regardless of whether the adverse events occur in formal clinical trials or in commercial use in Europe - the FDA had to have known about the adverse events of migration occurring in Europe which prompted the FDA to request an additional two-years of safety data from Endologix, delaying premarket approval for years. Defendants admitted on August 2, 2016 that they had submitted the European patient data to the FDA to serve as a basis, along with clinical trial data, in evaluating whether to grant Pre-Market Approval to Nellix.

27. Presumably, Defendants followed FDA regulations and disclosed the adverse events in Europe to the FDA. If the FDA was not aware of the adverse event reports in Europe that only meant that Defendants intentionally withheld that damning information from the FDA, thereby submitting an illegal PMA application.

28. Additionally, because Defendants knew that because migration was time dependent and incidents of migration drastically spiraled upward at 2 years of the device being implanted, the FDA could not and would not approve Nellix at the end of the two-year clinical studies but would instead request several years of follow-up data.

29. Analysts reacted harshly to Defendants' announcement that Nellix would not be approved consistent with the timeline Defendants represented to investors, noting the Company's about-face on the issue of migration, which "in the course of three weeks…has gone from 'its not a big deal' to 'it may end up impacting the business.'"

30. Another shoe was yet to drop. On May 17, 2017 Defendants provided an "update" on Nellix and revealed to investors that they would not be seeking FDA approval of the Nellix "first generation" device but instead intended to seek FDA approval of a second generation Nellix device. This would require a confirmatory clinical study and would push potential FDA premarket approval out to the year

2020. On this news, Endologix's share price fell over 36% or $2.47 per share, damaging investors.

JURISDICTION AND VENUE

31. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

32. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

33. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Defendants conduct business and operate facilities in this district, and a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

34. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

35. Court appointed Lead Plaintiff Vicky Nguyen, as set forth in her PSLRA Certification previously filed with the Court (Dkt. No. 18-2) and incorporated by reference herein, purchased Endologix securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

36. Defendant Endologix develops, manufactures, markets, and sells medical devices for the treatment of abdominal aortic aneurysms in the United States and internationally. The Company is incorporated in Delaware and its principal executive offices are located in Irvine, CA. During the Class Period Endologix securities were actively traded on NASDAQ under the ticker symbol "ELGX."

37. Defendant John McDermott ("McDermott") has served as the Company's Chief Executive Officer ("CEO") and as a member of the board of directors of Endologix from May 2008 to the present. McDermott has over 20 years of executive management, sales, marketing and finance experience in the vascular device industry. Prior to joining Endologix, McDermott served as President of Bard Peripheral Vascular, a division of C.R. Bard Inc. Before that McDermott served as the President of Global Sales for C.R. Bard's vascular surgery and endovascular business.

38. Defendant Vaseem Mahboob ("Mahboob") has served as the Company's Chief Financial Officer ("CFO") from October 2015 to the present. Prior to joining Endologix, Mahboob was the Chief Financial Officer of GE Healthcare's Global IT business. Mahboob received a B.A. in Engineering from Bangalore University and an MBA from the State University of New York, Buffalo.

39. Defendants McDermott and Mahboob are collectively referred to hereinafter as the "Individual Defendants."

40. Endologix, McDermott and Mahboob are collectively referred to hereinafter as "Defendants."

41. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

42. As officers, directors, and controlling persons of a publicly-held company whose common stock is and was registered with the SEC pursuant to the Exchange Act, and was traded on NASDAQ and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate accurate and truthful information promptly with respect to the Company's financial condition and to correct any previously-issued statements that had become materially misleading or untrue to allow the market price of the Company's publicly-traded stock to reflect truthful and accurate information.

43. Endologix is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

44. The scienter of the Individual Defendants and other employees and agents of Endologix is similarly imputed to Endologix under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Abdominal Aortic Aneurysms and the Nellix EVAS System

45. Endologix is a Delaware corporation with its headquarters and production facilities located in Irvine, California. Endologix develops and sells medical devices used to treat aortic disorders. Its products are intended for the minimally invasive endovascular treatment of abdominal aortic aneurysms ("AAA"), which is caused by Atherosclerosis.

46. Atherosclerosis is a disease which causes thickening and hardening of the arteries due to genetics, smoking, high blood pressure and/or high cholesterol damage. Atherosclerosis progresses with age and is estimated to affect 5%-6% of the population over 65.

47. Atherosclerosis weakens the walls of the blood vessel, causing the vessel to expand or balloon out. This expansion is known as an aneurysm. Aneurysms are most common in the aorta, the body's largest artery, which extends from the chest to the abdomen. The abdominal aorta is the segment between the renal arteries and the area where the aorta divides into two iliac arteries which travel down the legs. AAA occurs when a portion of the abdominal aorta bulges into an aneurysm because of a weakening of the vessel wall. This can result in life threatening internal bleeding upon rupture.

48. The treatment of AAA is difficult. Open surgical repair has a relatively high immediate mortality rate of about 4%, but if the patient survives the surgery, the repair will last reasonably well with low complication rates and requirement for secondary intervention. The first endovascular aneurysm repair devices- which stand in contrast to open surgical repair- reduced the immediate mortality rate to 1.8%, but were associated with higher complication rates, the need for long-term surveillance and high secondary intervention rates.[4]

[4] Endovascular versus Open Repair of Abdominal Aortic Aneurysm, The UK EVAR Trial Investigators NEJM 2010: 362; p. 1863-1871.

49. The overall patient mortality rate for a ruptured AAA is approximately 80%. Once AAA are diagnosed they require either non-invasive monitoring, or depending on the size and rate of growth of the AAA, either open surgical repair, endovascular repair or endovascular sealing. In addition to the risks, open surgical repair is a highly invasive procedure which requires a large incision, takes two to four hours and requires that the patient remain in the ICU for several days after the procedure. By comparison, the typical endovascular repair or endovascular sealing procedures last one to two hours, are minimally invasive, and allow patients to be discharged within a day or two.

50. Endologix estimates that approximately 70% of all AAAs in the U.S. are repaired through endovascular repair and 30% through open surgical repair.

51. Endologix's AAA products, which are the sole source of its revenues, are built on one of two systems: (1) the "traditional" minimally-invasive endovascular repair ("EVAR") or (2) the innovative solution for sealing the aneurysm sac, endovascular sealing ("EVAS").

52. Endologix estimates that the AAA market potential is $2.7 billion.

53. Endologix's AAA products are medical devices which require FDA approval for marketing in the United States. Endologix's product for endovascular sealing is called the Nellix EVAS System. The Nellix EVAS System is Endologix's innovative solution for sealing the aneurysm sac. The Nellix EVAS System required Premarket Approval ("PMA") before it could be marketed in the United States.

54. PMA is the most stringent type of device marketing application required by the FDA. A PMA is an application submitted to the FDA to request approval to market a device. Unlike premarket notification, PMA approval is to be based on a determination by the FDA that the PMA contains sufficient valid scientific evidence

that provides reasonable assurance that the device is safe and effective for its intended use or uses.[5]

55. A PMA application is required to contain the device's indications for use, defined as "[a] general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended. 21 C.F.R. (3)(i).

56. A medical device's "indications for use" or "IFU" dictates the patient population that can be treated with the device. The broader the IFU or patient population that the device can be used in, the greater the potential sales of the device and of course this means greater revenue for the company marketing and selling the device.

57. The purpose of the PMA application is to provide the FDA with as much information as possible to evaluate the safety and effectiveness of a device. Specifically, the PMA application submitted to the FDA ***must*** include the following information: "An identification, discussion and analysis of ***any other data, information, or report relevant to an evaluation of the safety and effectiveness of a device*** known to or that should reasonably be known to the application from any source, ***foreign or domestic***, including information derived from investigations other than those proposed in application and from commercial marketing experience." 21 C.F.R. 814.20(b)(8)(ii) (emphasis added).

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[5] The review of a PMA is a four-step review process consisting of: 1) administrative and limited scientific review by FDA staff to determine completeness (acceptance and filing reviews); 2) in-depth scientific, regulator, and Quality System review by appropriate FDA personnel (substantive review); 3) review and recommendation by the appropriate advisory committee (panel review) and 4) final deliberations, documentation and notification of the FDA decision.
See PMA Review Process 21 C.F.R. 814.42 et seq. available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm

58. In addition, the PMA application instructions state: "It would be appropriate to include … a summary of any adverse experiences reported … ." 21 C.F.R. 814.20(b)(3).

59. Simply put, the lynchpin of FDA approval is the safety of a device. If a device is shown to be unsafe based on adverse events it is irrelevant where those adverse events occurred or were reported or whether those adverse events did or did not occur in the context of a controlled clinical trial.

60. Consistent with the requirements set forth in 21 C.F.R. 814.20(b)(8)(ii), Defendants were required to disclose to the FDA the adverse events and complications with the Nellix EVAS System as well as any patient or doctor complaints that occurred in Europe where Nellix had been marketed since February 2013.

61. Presumably, Defendants followed the requirements of 21 C.F.R. 814.20(b)(8)(ii) and did in fact submit to the FDA the adverse events and complications with the Nellix EVAS System as well as any patient or doctor complaints that occurred in Europe. In the alternative, if Defendants did not do so they intentionally and illegally lied to the FDA by withholding information legally required to be disclosed, thereby submitting a false PMA application.

62. If the FDA rejects a PMA, a device manufacturer is always able to reapply for a PMA if it can successfully address the reasons for rejection. Likewise, if a clinical trial fails, a company can always seek to conduct additional trials or modify the device until the product works safely and effectively. However, in practice this means years of delay before the device will be approved for marketing and an even longer delay before commercial sales are achieved.

63. In the United States, Endologix markets and sells its products through a direct sales force. The primary customer and decision maker for its products is the

vascular surgeon. Approximately 70% of Endologix's revenues in the 2015 fiscal year were generated from U.S. sales.

64. Endologix also markets and sells its products in Europe, Asia Pacific, South and Central America and Mexico. In 2015 20% of Endologix's revenues were generated from sales in Europe.

65. Endologix's endovascular sealing or "EVAS" product consists of: (i) bilateral covered stents with endobags, (ii) biocompatible polymer injected in to the endobags to seal the aneurysm and (iii) a delivery system and polymer dispenser.

66. Endologix states that its Nellix EVAS product effectively seals the entire aneurysm sac excluding it and thereby reducing the likelihood of future aneurysm rupture, and also has the potential to reduce the need for post-procedural re-interventions. Endologix's sole EVAS product is the Nellix Endo Vascular Aneurysm Sealing System (the "Nellix EVAS System" or "Nellix").

67. One of the biggest issues with medical devices used for endovascular repair is "endoleaks." Once a device is placed in a patient with an abdominal aneurysm a leak of blood from above or below the device or from its side branches can occur, requiring re-hospitalization to repair or replace the device.

68. Another potential serious adverse event that can occur with medical devices used for endovascular repair is "migration" where the medical device moves or migrates from where it was initially placed.

69. Endologix claims that the Nellix EVAS System meets the unmet needs of other endovascular repair systems because it is the only device that is designed to fill the aneurysm space with a biostable polymer and seal the aneurysm sac and prevent leaks, thereby reducing endoleaks and reinterventions.

70. Additionally, one of the selling points of Nellix was that it could be used for a broad range of anatomies. For example in a November 20, 2013 investor

conference call Defendant McDermott stated "***we plan to broaden Nellix's indication beyond any of the other endovascular aneurysm devices.***" (emphasis added).

71. A broad IFU meant not only increased commercial appeal for the product to investors and consumers but increased market share for Defendants. The more patients with AAA that could use Nellix, the greater the number of units of Nellix Endologix could sell, and the greater the revenue and profits for Endologix and the Individual Defendants.

72. Increased commercial appeal for Nellix also meant increased interest in Endologix stock by investors and a higher Company stock price.

73. In February of 2013, Endologix received "CE Mark" approval in Europe for the Nellix EVAS System and commenced a limited market introduction in Europe of the Nellix EVAS System. CE marking is a mandatory conformity marking for certain products sold within the European Economic Area. CE marking is the manufacturer's declaration that the product meets the requirements of the applicable European Commission directives. Unlike FDA approval in the U.S., CE marking indicates that a given product is safe only, whereas FDA approval in the U.S. requires a showing of both safety and effectiveness. Generally, CE marking is thought to be a much quicker, less rigorous process than FDA approval.

74. In December of 2013 Endologix received Investigational Device Exemption ("IDE") approval from the FDA to begin a clinical trial for the Nellix EVAS System. The clinical trial, called the "EVAS Forward IDE" began in January 2014, and enrollment in the study was completed in November 2014. By November of 2016 two full years of data from the EVAS Forward IDE was available to Defendants.

75. The EVAS Forward IDE consisted of 179 patients at 29 centers in the U.S. and Europe, of which approximately 25 were in the U.S. Each patient would be followed for one year, after which Endologix would submit the final module of the

PMA to the FDA. Endologix received approval to enroll additional patients in the trial in the third quarter of 2015.

76. An additional international study, the "EVAS Forward Global Registry" was put in place by Endologix to "provide real world clinical results to demonstrate the effectiveness and ***broad applicability*** of the Nellix EVAS System." The registry was designed to include 300 patients enrolled in up to 30 international centers. The first patient in the registry was treated in October 2013 and patient enrollment was complete in September 2014. (Emphasis added). By September of 2016 two full years of data from the EVAS Forward Global Registry was available to Defendants.

77. Endologix competes with much larger companies such as Medtronic, and the successful development of a rival EVAS system by competitors was seen as a major risk to Endologix by analysts and investors. Accordingly, Defendants were in a race to make Endologix the first company to receive FDA PMA approval to sell and market an EVAS system, i.e. Nellix, in the United States.

Anticipated FDA Approval of the Nellix EVAS System

78. Analysts and investors eagerly anticipated the FDA approval and the U.S. launch of the Nellix EVAS System. The Nellix EVAS System was Endologix's primary selling point to investors leading up to and during the Class Period. For example, an April 1, 2016 JPMorgan analyst report stated "We believe the company could be on the cusp of another significant growth phase as its next-gen platform, Nellix, works toward a possible FDA approval in 2H16. Nellix has the potential to be a disruptive new technology, in our view, introducing the concept of endovascular aneurysm sealing, or EVAS, to the field of AAA repair…Buoyed by Nellix, our model calls for Endologix's US market share to rise from 14% in 2015 to 18% by the end of the decade, driving a significant reacceleration in the company's overall top

line growth profile over that period. ***We expect Street sentiment to improve as FDA approval for Nellix draws closer*** and investors gain further visibility into this growth acceleration. As a result, we assign ELGX shares our Overweight rating." (Emphasis added).

79. Analysts again noted the tremendous market opportunity for Endologix given Nellix's potential to treat complex anatomies, given its broad IFU. An August 6, 2015 JP Morgan analyst report states "Combined with its ***ability to treat a wider range of anatomies*** than the traditional EVAR systems, we believe this ***clinical advantage*** gives Nellix the potential to be a disruptive new entrant to the market."

80. In an October 6, 2015 JP Morgan analyst report entitled "Endologix-One to Own in 2016; Nellix US Launch Analysis Reinforced Our Bullish Thesis," JP Morgan analysts stated: "roughly half of all patients diagnosed with AAA have short necks ***or other types of challenging anatomy that make them difficult to treat with traditional grafts.*** Penetration of this ***$1.6B market opportunity*** stands at just 20-25% today, suggesting ample room for market expansion a technologies that more effectively address these patients come to market. ***We believe that Nellix can be that product***." In the EVAS FORWARD Global Registry, 35% of patients treated with Nellix had complex anatomies, ***including many who would not have been able to be treated endovascularly otherwise. Nellix performed admirably in this challenging population.***" (Emphasis added).

81. As Defendant Mahboob stated, the Nellix EVAS system represented a massive opportunity for Endologix: endovascular sealing purported to mitigate many of the deficiencies of endovascular repair, such as migration (i.e. movement of the device away from location of implant inside the patient's body, which can result in catastrophic consequences) and endoleaks. As Mahboob stated at the May 5, 2016 Deutsche Bank Health Care Conference, "***we're trying to redefine the entire endovascular repair into endovascular sealing as we call it***." (Emphasis added).

82. Defendants represented that the Nellix EVAS System was slated for FDA approval in the United States by the fourth quarter of 2016. Discussing the data from the EVAS Forward Global Registry at a May 5, 2016 Deutsche Bank Health Care Conference, Defendant Mahboob stated "the data continues to be spectacular on the Registry. What we realized on the Registry was that our persistent endoleak rate was 1.9%, and by the way, on a pretty broad range of patients, five endoleaks in total, which is unheard of. The competitive rates are up to 10% and we are at 1.9%."

83. With respect to FDA approval Mahboob stated: "we feel pretty good about the timeline that we've been putting out consistently for the last six months to eight months, which is that we expect the approval to be in the Q4 to latest Q1 timeframe. The one big piece of data is going to be presented at SVS [Society for Vascular Surgery], which is on June 11 here in Boston, is the data for the IDE clinical data, which is going to be presented. And that's going to happen in June. So again, on track from a PMA milestone perspective for a Q4 approval." (Emphasis added).

84. On May 9, 2016 during Endologix's First Quarter 2016 investor conference call McDermott misrepresented to investors that things with Nellix were rolling along smoothly, stating "Nellix is doing as expected. No surprises." Mahboob misled investors to believe that Nellix's performance in Europe was fantastic.

85. Further underscoring the importance of the Nellix EVAS System at the May 10, 2016 Bank of America Merrill Lynch Health Care Conference McDermott touted its uniqueness and advantages:

> And then last but not least is Nellix. ***So, Nellix is really the next-generation platform in aneurysm repair.*** What's unique about Nellix is it's the only device that completely fills the aneurysm space and seals the aneurysm. So, the biggest failure mode for these devices is what we call endoleaks. So, that is leaking blood into the aneurysm sac. You're trying to seal that aneurysm sac, that pressurized blood flow off the

> aneurysm. If you have a leak it can pressurize the aneurysm sac. The aneurysm can grow and lead to rupture which is what we're trying to prevent. ***By sealing off the entire aneurysm, we can get the lowest rate of endoleaks ever reported, and that's the unique value proposition of Nellix.***
>
> [Emphasis Added]

86. Defendant McDermott went on to discuss the data from the EVAS Forward Global Registry:

> Just a little bit of clinical data on Nellix…this is a cut of 18-month data….ACM stands for all-cause mortality. Type II endoleaks, that's an endoleak into the aneurysm sac from side branches and then total endoleak. So if you just look at these categories, that's just getting compared- wasn't a comparative trial but another large post market registry called ENGAGE from Medtronic, not as complex anatomies but it's the best comparison that we have. This is two-year data compared with our 18-month data. So there is a little bit of a time difference. But as you can see, the all-cause mortality rate with Nellix is considerably lower as is the type II endoleak rate and the total endoleak rate. So this is why there's so much interest in Nellix, it really has the potential to be a game changer. In terms of our PMA, as I mentioned, on June 11, the one-year data from our IDE clinical trial would be presented for the first time at the Society of Vascular Surgery Meeting in Washington, D.C. We have already submitted the modules of the PMA and, in fact, last week, got notification from the FDA that they've accepted all the modules, and that have what they need to continue the review. So we'll present that data in about a month, and then ***we expect the PMA approval around the end of this year, first part of next year***. Our 100-day meeting, which is where we'll find out whether or not we have to go to panel, will occur by the end of July. So, that's kind of the timeline so far. Everything is clipping along nicely.

87. Then, on May 26, 2016 Endologix released the purportedly positive results from the Nellix EVAS Forward IDE trial, highlighting the following clinical data:

- 150 patients in the pivotal cohort were treated at 30 centers in the US and Europe between January and November 2014.
- 100% procedural technical success achieved.
- The major adverse event (MAE) rate at 30-days was 2.7%, achieving the primary safety endpoint and comparing positively to the Society for Vascular Surgery (SVS) open surgical repair control group rate of < 56%.
- At the year, the treatment success rate was 94%, achieving the primary effectiveness endpoint and comparing favorably to the performance goal of > 80%.
- Freedom from all-cause mortality and AAA-related mortality were 96% and 99% respectively.
- Freedom from device related secondary interventions was 96.6%, the highest rate ever reported for an IDE study of an endovascular AAA device.
- Endoleaks were present in 3.1% of patients at 1-year, the lowest rate ever reported for an IDE study of an endovascular AAA device.

88. On June 11, 2016, the results of the EVAS Forward IDE Study were submitted to the FDA as part of the Company's PMA submission for the Nellix EVAS System. The Company represented that it remained on track to receive FDA approval for the Nellix EVAS System at the end of 2016 or early 2017.

89. Then, on August 2, 2016, with anticipated FDA approval nearing closer, Defendant McDermott announced the Company's results for the second quarter of 2016, reiterating the likelihood of forthcoming FDA approval of Nellix in the U.S. and the growth for the Company as a result stating "we remain very positive about

the likelihood of approval [for Nellix EVAS System] and the significant growth we expect to drive with Nellix."

90. Defendant McDermott also assured investors on the August 2 call that no issues existed with the data from the Nellix EVAS System IDE Study, after the FDA expressed the possibility of referring the Nellix EVAS PMA to Panel Review.[6] Panel review would delay FDA approval by about two fiscal quarters (six months) but does not necessarily affect the issue of whether a device is approvable *per se*. McDermott's colloquy with investors was, in pertinent part, as follows:

> **Matt Blackman**
> Okay, that's very helpful. And I'm going flip in one last question back on the panel. ***I'm sure you're eager to provide the intimate details of your FDA discussions…But maybe give us a little bit more color, more sense of comfort that there is not something else going on, there is no sort of red flag raised in terms of data that they saw. I guess, anything that you could give us that, gives us any comfort there would be helpful?*** Thank you.
>
> **John McDermott**
> Sure. So, the three reasons that the agency will typically consider sending a device to panel is one; if there is, any new clinical issues of safety [or] efficacy and obviously ***everyone has seen the data so we know there aren't any issues there*.** The second reason is if they feel - the FDA feels they don't have the clinical or technical expertise to complete the review of a PMA, that's not the case. So and the third is if it's novel technology.

[6] The FDA may refer the PMA to an outside panel of experts (advisory committee). In general, all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel for review and recommendation. However, as soon as FDA believes that (1) the pertinent issues in determining the safety and effectiveness for the type of medical device are understood and (2) FDA has developed the ability to address those issues, future PMAs for devices of that type are not be taken before an advisory panel unless a particular application presents an issue that can best be addressed through panel review. 21 C.F.R. 814.44.

[Emphasis added].

91. Defendant McDermott further went on to provide additional assurance to investors on the August 2 conference call that none of the questions the FDA posed to the Company detracted from the approvability of the Nellix EVAS System, stating in pertinent part:

> **Joanne Wuensch**
> Hi. Can we talk a little bit about what type of additional data or questions that you're receiving? I mean, is there any way to give us some information regarding that?
>
> **John McDermott**
> Yes, I don't want to get too detailed with that Joanne. What I can tell you, is that ***none of the questions we got asked are what I would characterize as big surprises***. There is clarification on some things, some requests for additional analysis, some additional testing. ***Nothing that would suggest in our view any question or risk of approvability, just some more blocking and tackling and clarification of the data we submitted***.
>
> ***So, we don't see anything in there that's given us heartburn***. It will just take a little time to pull it altogether. And we'd also like to take another run at this novelty question and see if we can provide the agency with enough evidence that the device isn't novel so that we don't have to go to panel. So that would be the focus of the work we do over the next few months.

[Emphasis added].

92. On November 1, 2016, during aftermarket hours, the Company held a conference call with investors to discuss the Company's financial results for the quarter ended September 30, 2016. During the November 1 Conference Call,

Defendant McDermott touted the Company's positive interaction with the FDA, stating in pertinent part:

> **John McDermott**
> In terms of the U.S. PMA, we achieved the clinical endpoints in the IDE share dilated clinical data with FDA. We've also provided them with our updated patient selection criteria and **have had positive discussion so far**. Nellix PMA approval time lines are unchanged although we think a panel is more likely now given the updated indications.
>
> [Emphasis added].

The Nellix EVAS System and Migration

93. The FDA defines migration as a problem with an implanted or invasive device moving within the body, or being completely expelled from the body.[7]

94. Migration, if untreated, can result in a type I endoleak (blood flow into the aneurysm sac due to incomplete or ineffective seal at the end of the graft), aneurysm expansion, and rupture as its most catastrophic consequence.[8]

95. A 2016 Case report from the United Kingdom warned of the ominous risks of migration of the Nellix EVAS System[9]. The case report cited a 2016

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[7] https://ncit.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&version=16.10e&code=C62917&ns=NCI_Thesaurus

[8] Mid and long-term device migration after endovascular abdominal aortic aneurysm repair: A comparison of AneuRx and Zenith endografts, 2005, Journal of Vascular Surgery, Vol. 42, Issue 3, p. 392-401.

[9] Vasa (2016,) 45(6), 505-07. "Case Report: Nellix stent graft migration after endovascular aneurysm sealing", George A. Antoniou, Khalid Bashaeb, and Riza Ibrahim, published Aug. 29, 2016.

University of Liverpool study of 18 patients consisting of 35 stent grafts[10]. In that study, the migration rate of the Nellix EVAS System was 17% (migration occurred with 6 out of the 35 devices), compared to the 2.3% migration rate reported in the Nellix EVAS IDE Study. The Case report discussed a patient whose aneurysm was treated with the Nellix EVAS System. In that patient, the Nellix EVAS device was explanted after the device migrated 11 mm and the aneurysm sac expanded, with case study authors noting that "in retrospect, we think that earlier intervention should have been undertaken to mitigate the risk of a catastrophic event."

96. The study concluded that "In the absence of a proximal fixation mechanism in EVAS, migration of the Nellix system should represent a more ominous sign, which would complicate a persistent type I endoleak resulting in continued aneurysm growth and inferior translocation of the stents within the aneurysm sac. EVAS has failed to obliterate the long-term complication seen with conventional endovascular treatment…"

97. Defendants explained away the ominous findings of the above Case report. Addressing an analyst's question concerning migration on a June 11, 2016 Endologix conference call to discuss the "positive clinical data from the Nellix EVAS Forward-IDE Study" Defendant McDermott stated: "one point about the Liverpool paper as a reminder is they chose to define migration as 4 millimeters which is less than half of the SVS definition and also found the same that we found so far in the IDE at one year, they had no reinterventions or endoleaks or even events related to those imaging findings."

98. The issue of migration with Nellix EVAS System again came up after Endologix told investors in its November 1, 2016 investor conference call, that the FDA requested that Endologix submit "the most recent cut of the data for them to

[10] J Vasc Surg. 2016, Aug; 64(2) 306-312 "Migration of the Nellix endoprosthesis". England A., *et al*., published Apr. 9, 2016.

review," and that Endologix had changed the Indication For Use ("IFU") for Nellix EVAS based upon the "updated data cut" that Endologix had recently run. Defendant McDermott stated:

> Regarding Nellix, we've recently ran an updated data cut from the IDE clinical database and noticed an increase in migration in aneurysm enlargement in some patients with two-year follow-up. We're learning that migration can occur in patients with small flow lumens and a lot of thrombus because there isn't enough space to inject sufficient polymer to support the stents. Our solution is a simple update to the patient's selection criteria that measures the ratio of aneurysm diameter to the flow lumen to ensure there is enough space for polymer…When we examined the IDE data for patients that fit within this updated selection criteria, we see extremely positive safety and durability results out to two years, which gives us confidence that Nellix can be a leading device in the treatment of abdominal aortic aneurysms.

99. Presenting the issue of migration with the Nellix EVAS System as a problem that had only recently come to Defendants' attention, and one with an easy fix, Defendant McDermott went on to emphasize Endologix's favorable interactions with the FDA and downplayed any concerns regarding migration stating, "we did have a successful clinical study and met the endpoints in the trial. So actually when we interacted with the agency so far on the updated indications, they've responded favorably. They had some questions about migration and a curiosity if it was progressive…we really can't get into any of the data details as this point in time…But what I can tell you is that the re-interventions related to this issue are extremely low." McDermott also emphasized that the issue of migration was "a very easy situation to address just by narrowing for those particular anatomies" adding that "I think people are – have given us a lot of credit for being so proactive and getting out ahead of it. We'll say there are some physicians who think we're being a little conservative, but

our view is let's be- let's think patient safety first and then we can see some ways to open up this patient criteria moving forward."

100. Finally, McDermott assured investors that "the Nellix PMA approval timelines are unchanged, although we think a panel is more likely now given the updated indications. We estimate the panel meeting will be in April or May, which would lead to a potential PMA approval in the third quarter of 2017."

101. While Defendants portrayed the issue of device migration as no big deal with an easy fix, the reality was starkly to the contrary. And while Defendants claim to have taken note of migration with the Nellix EVAS System based upon running a "recent data cut" the persistent problem of Nellix and migration was not only well-known by Defendants since the beginning of 2015 but it was an intractable, unresolvable problem that plagued Defendants constantly. Additionally, Endologix's top scientists had urged Defendants to issue the revised IFU at least one year prior, after discovering that Nellix was particularly dangerous in patients with a lot of thrombus. Defendants refused, putting patients' lives at risk.

102. While the clinical studies of Nellix were supposedly going "as expected", patients in Europe, where Nellix had been sold for over three years, were experiencing serious adverse events.

103. Defendants received an abundance of documented evidence showing that Nellix was migrating, or moving from the location where it was implanted in patients' bodies, which can lead to catastrophic consequences.

104. Endologix's top scientists were singularly focused on this migration problem and were unable to find a solution or a cause. Of course, this had implications for FDA approval of Nellix in the U.S. irrespective of whatever the limited U.S. study showed since the FDA would not approve a device that was fundamentally unsafe. If Nellix was unsafe for European patients it would prove equally unsafe for U.S. patients.

105. Confidential Witness 1 ("CW1") is Endologix's former Director of Research and Development who subsequently became the head of Aortic Procedure Development at Endologix. CW1 was employed at Endologix from January 1, 2011 through June 2016. CW1 was personally hired by Defendant McDermott and reported to Chuck Love, Vice President of Clinical Affairs. CW1 explained that he came to work at Endologix because of his relationship with McDermott, whom he had known for 30 years. CW1 explained that McDermott recruited CW1 to work at Endologix, at the Company's Irvine, CA corporate headquarters specifically to work on Nellix from its inception. CW1 worked on the development of Nellix, including testing and procedures, and stated that he was "a developer, trainer, did clinical trials. I was very involved with Nellix right from the beginning."

106. CW1 described the Company's push for testing and implementation of the Nellix EVAS System in Europe as being "an exciting time" consisting of a good team effort: "I came because of my relationship with John [McDermott] and he wanted me to help everything get straightened for Europe. That's trials, approvals, partners, that type of thing." CW1 stated that he built relationships with doctors throughout Europe, including with Dainis Krievens, a Latvian vascular surgeon who became one of the first users of the Nellix EVAS System. CW1 states that "At first Dainis was reporting very good results, and we were all very encouraged. There were some problems, leakage, very limited migration. Things that caused us to pay attention but completely in line with what you'd expect at that state of the trials."

107. However, CW1 reports that in early 2015 Endologix started getting more reports of problems involving migration of the Nellix EVAS System from doctors throughout Europe. CW 1 explained that as reports of migrations began multiplying, CW1, Chuck Love, the Vice President of Clinical Affairs and Avyaya Sharma, the head of Global Clinical Affairs, along with many others working on the Nellix EVAS System, feverishly worked to find commonalities and possible causes for the

migrations. CW1, Love and Sharma were in constant contact with European doctors and partners reviewing the "stream of complaints and incident reports" coming in, which were all linked to migration issues.

108. CW1 states that a turning point with respect to the Nellix EVAS System and migrations occurred in the fall of 2015: "By I'd say October, maybe November of 2015, it hit an inflection point and everything changed. We had a serious problem and everyone was on it. That's when John [McDermott] and Vaseem [Mahboob] got very involved.

109. CW1 reports that in December 2015 McDermott convened a series of meetings with senior staff to discuss the problem of migration with the Nellix EVAS System. These meetings were attended by McDermott, CW1, Avyaya Sharma (head of Global clinical affairs), Chuck Love (Vice President of Clinical Affairs), Jose Lima (Vice President of Quality) and Afir Iftekhar (Thoracic Therapies Business Leader). CW1 stated that "John McDermott knew just how serious this was, and Jose [Lima] is a very smart man, so John had him running our research."

110. CW 1 reports that Lima and Iftekhar both stayed directly involved in trying to solve the Nellix EVAS migration problem for several months and CW1 communicated constantly with European doctors who were using the Nellix EVAS System. CW1 states that not only could the Company not find a solution to the migration problem, but they could not even figure out what was causing the devices to migrate in the first place: "We had endless meetings analyzing every data point from every patient to see if we could predict when these things were going to migrate. The whole year and a half we were investigating, I don't think there was any progress. This consumed all of [us] every day. We literally spent thousands of hours on this, and generated thousands of pages of paper with studies and reports. ***And John [McDermott] and Vaseem [Mahboob] were given everything. They had to be***

because this was the biggest thing we had going at the company." (emphasis added).

111. As referenced above, in November 2016 the Company, for the first time, revised the Indications for Use ("IFU")[11] for the Nellix EVAS System and made doctors and the public aware of the migration issue through issuance of field safety notices. CW1 reports that this could and should have been done far earlier, in 2015, when Defendants became aware of the migration problems. The revised IFU narrowed the patient population to exclude patients with thrombosis from using the Nellix device. The revised IFU also significantly diminished the patient population that could use Nellix, undermining Nellix's selling point as a one-size fits all device that could be used to treat patients with complex anatomies.

112. CW1 reports that he, along with Chuck Love and Avyaya Sharma personally pushed McDermott to modify the IFU in November 2015 but that McDermott refused: "One problem I had, and so did Chuck Love and Avy [Sharma] was that we didn't issue any FSN (Field Safety Notices) or IFUs, to make doctors aware of the problem. I read the FSN they [Endologix] sent out in November [2016]. ***That FSN should have been issued at least a year earlier. We pushed John to do that and he wouldn't***." (emphasis added).

113. Revising the IFU would reduce the patient population that could use the device by a significant percentage. Approximately 37% of the patients enrolled in the clinical trials would have to be eliminated because they did not fit the narrowed IFU.[12] Narrowing the IFU would have required Endologix to enroll more patients in

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[11] An IFU describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the target patient population.

[12] According to a January 1, 2017 presentation by Matt Thompson 37% of all patients treated in the Global Registry had complex anatomies outside of the IFU. https://linc2017.cncptdlx.com/media/0944_Matt_Thompson_25_01_2017_Room_2_-_Main_Arena_2.pdf

the clinical studies being submitted to the FDA, to make up for patients who were eliminated from the studies because they did not fit the revised criteria. Accordingly, revising the IFU would significantly delay PMA approval given that data on newly enrolled patients would not be available until two years after the date on which they were enrolled.

114. CW1 confirmed that as the investigation into migration of the Nellix EVAS System continued at the Company, Endologix's scientists found that the Nellix EVAS System was particularly dangerous in certain indications, specifically patients with thrombosis, and that upon discovery of this the Company should have, but did not, issue immediate field safety notices.

115. Thrombosis is the formation or presence of a blood clot in a blood vessel. The vessel may be any vein or artery. The clot itself is termed a "thrombus."

116. CW1 reports that in the early months of 2016 CW1, Sharma, Love and others began compiling multiple reports and presentations *per week* for McDermott and Mahboob concerning migration of the Nellix EVAS System in anticipation of the Company's annual Symposium on Sealing Aneurysms ("SAS"), held on March 10-11, 2016 in London.

117. While the SAS was attended by experts in the field of endovascular aneurysm sealing it was not a public event. No articles or meeting minutes from SAS were publicly released to investors or the public, and Defendants never publicly discussed the SAS.

118. CW1 states that he spent a lot of time in Europe leading up the SAS conference and that at this time the reports of migrations with the Nellix EVAS System from doctors increased even more.

119. CW1 explained that at the SAS Endologix's scientists, directors, and Lima and Iftekhar provided full and honest discussion and responses to questions concerning migration. CW1, along with Sharma and others provided input into the

presentation which Iftekhar was put in charge of creating which documented the clinical data and the scope of the migration problem. Defendant McDermott signed off on the presentation along with all of the statements by Endologix directors and scientists set to speak.

120. CW1 attended all of the discussions and presentations at the SAS in March 2016. He stated that Matt Thompson, who was then a Company consultant and is now the Company's Chief Medical Officer was very upfront and stated: "We are having some unexplained migrations, a lot of them. It looks like we've done everything perfect, there aren't any defects or things we can point to. They are still slipping down."

121. The Company's official presentation at SAS was given by Iftekhar, CW1 stated. His presentation was titled "Migration after EVAS" and CW1 recounted that Iftekhar once bluntly stated that the Company had no solutions to the problem of Nellix EVAS migration. The Company's official presentation at SAS was not disclosed to the public.

122. CW1 further stated that the most important and detailed presentation at SAS was given by Latvian vascular surgeon, Dainis Kreivens, one of the earliest users of the Nellix EVAS System. CW1 described Krievens as "the smartest man in the world" to whom "people paid a lot of attention." CW1 stated that Krievens "has data from the very early days, very distinct information on different types of cases", and that Kreivens said, "'look, these things are slipping, they are moving, and it is happening in a lot of cases.'"

123. CW1 added that after Dr. Kreivins' presentation at the SAS, Krievens met with him (CW1) and other top people at Endologix such as Matt Thompson and Afir Iftekhar and said, referring to Nellix EVAS System migration, "'look, I'm telling you now, this is not good.'" CW1 reports that Krievens characterized the situation as "urgent".

124. CW1 states that after the SAS in March 2016 he returned to Endologix's headquarters in Irvine, CA where he, along with Sharma and Love met with Defendant McDermott and relayed Dr. Krievens' very pointed warning. CW1 reports that at that meeting, CW1 and McDermott discussed issuing field safety notices concerning migration and new use instructions to doctors and researchers. CW1 states that he was encouraged by the honesty at SAS: "It seemed to be the turning point where we were going back to being the company we were. It was late but we were relieved."

125. However, the field safety notices and revised IFU for Nellix EVAS that CW1, Defendant McDermott, Thompson and Iftekhar discussed were not then issued and the Company was silent on the massive problem of migration.

126. CW1 describes his and his colleagues' disgust when they listened to McDermott tell investors, on the Company's First Quarter 2016 earnings call on May 9, 2016, (nearly two months after the SAS) that "Nellix is doing as expected. No surprises."

127. CW1 describes listening to the Company's May 9, 2016 earnings call, during which the word "migration" was never mentioned: "We were disgusted. All of us were sitting around listening to the call, and we were shocked. People were already leaving the company because of the awful transition with the acquisition of TriVascular, but that earnings call led a race to the door. We all wanted out."

128. CW1 stated that Defendants continued to mislead investors. For example, during the Company's August 2, 2016 Second Quarter 2016 investor conference call, McDermott stated that no issues existed with the data from the IDE Study. Reacting to this, CW1 stated that this "could not have been further from the truth. By the time of the call we had been working for seven or eight months extensively on the migration issue, and John [McDermott] was involved with, or given very detailed reports, about every aspect. ***He knew that we had serious issues***

that we just weren't able to overcome…[h]e lied about pretty much everything." (emphasis added).

129. Elaborating on the abundance of information in Defendants' possession concerning the undisclosed severity and extent of the migration issue, CW1 went on to state: "We literally have years of complaints, questions from doctors, clinical studies. We've known since 2015, maybe even a bit in 2014, about the migration issue. We didn't know how bad things were at first, and then we spent everything trying to figure out the cause. All of that is documented. Every single thing…There is a thorough database. Every time a doctor made a complaint, or reported patient follow up, it was measured and recorded. Then, you have to get the clinical trial database. All of these records are very detailed, and they will show that John [McDermott] and Vaseem [Mahboob] knew about all of the problems and they kept lying to shareholders."

The Truth Comes to Light

130. On November 16, 2016, before market hours, Endologix issued a press release entitled "Endologix Provides Update on Nellix PMA Process," revealing that Nellix EVAS would not receive FDA approval consistent with the "timeline" that the Company had promised investors. Instead, the FDA had requested that the Company provide 2-year patient follow-up data from the Nellix EVAS Forward IDE Study. According to the Company this would mean that potential FDA PMA approval of Nellix could not occur until the second quarter of 2018, delaying approval at least an additional 18 months based upon the planned 4th quarter 2016 approval the Company had previously announced.[13] McDermott stated: "we're disappointed by these

[13] According to an August 3, 2016 JP Morgan analyst report, each quarter that approval is delayed represents roughly $7 million in revenues lost. Endologix's total revenue for the second quarter of 2016 was $51 million. This meant a 14% decline in expected revenue each quarter for at least another two years.

requirements and the resulting delay, but encouraged by the 2-year clinical outcomes we have seen so far with Nellix under the newly revised instructions for use. We remain committed to EVAS and Nellix and have demonstrated outstanding clinical results in selected patients with both traditional and complex AAA anatomies."

131. In reality, this was no surprise to Defendants. CE Mark approval obtained in Europe February 2013. CW 1 said reports of migration problems were "multiplying" by early 2015. Early 2015 is the end of the 2 year mark, meaning Defendants knew by no later than early 2015 that migration was a severe threat to PMA approval in the U.S, and would also affect sales of Nellix in Europe.

132. By November of 2016 the IDE Study and Global Registry had been going on for two years. Defendants knew from their experience in Europe that it was between years 1 and 2 of implantation with Nellix that device migrations began to occur, spiking dramatically towards the end of the second year of implantation.

133. Despite the Company's attempt to whitewash the situation, on this news, shares of Endologix fell $2.02 per share, or over 20.5%, from its previous closing price to close at $7.82 per share on November 16, 2016, trading at ***over twelve times the volume from the day prior***.

134. The next day Endologix held its 2016 Investor Meeting. McDermott presented as new information what Defendants had known and hid from investors for over a year: that there was a problem with Nellix EVAS System and migration and that as a result the FDA required additional data to determine the real patient risk from migration before it could consider approving the device:

> Analyst:
>
> …were there migration issues in that subset of patients that the FDA already saw and is that why they're saying give me the two years for everybody?

> John McDermott:
>
> Yes. So everybody saw the one-year data which was 2.3% of patients had a 10 millimeter migration or more at one year. What we saw was when we did an updated data cut for our response, some of those patients went on to migrate more and there were some patients ***that hadn't displayed any migration at one year that showed signed of migration in year two.***
>
> And although most of those findings were still hadn't triggered interventions, there were some and I'm not going to tell you there were zero intervention. I honestly, right now, don't know the exact number off the top of my head, but it was really the change in the rate. It was the increase in the rate from year one to year two and that's what drove the discussion.

(emphasis added)

135. Defendant McDermott explained the FDA's reason for why the FDA demanded an additional two years of clinical data before it would consider approving Nellix. In doing so, McDermott presented as new information to investors what Defendants had known and hid all along: the evidence of migration from the IDE Trial, Global Registry and direct channel experience in Europe meant that the FDA would need more clinical data to determine the real patient risk from migration. As Defendant McDermott stated "it was the increase in the rate from year one to year two." *Id.* As in Europe, where Nellix had good results early on and migration did not occur until Nellix had been implanted for over a year, migration complications in the U.S. clinical data did not arise until later on, specifically after at least a year following implantation.

136. Analysts took note of Defendants' about-face concerning the issue of migration and its impact on the Nellix EVAS System and its timeline for FDA approval. On November 18, 2016, a JP Morgan analyst stated:

> At the forefront of investor's minds into the meeting was Wednesday's announcement that the FDA is raising the bar on Nellix's filing, asking for 2-year follow-up data from the company's EVAS FORWARD trial and effectively pushing out a US approval to at least 2Q18. ***In the course of three weeks, the Nellix Dear Doctor letter and IFU change has gone from 'it's not a big deal' to 'it may end up impacting the business.'*** Management lowered the top-end of its 2016 revenues guidance by $1M to 198-200M and reset expectation for 2017 to the lower-end of its 5-10% commentary following the 2Q call, all of which points to incremental concerns about Nellix post- the Dear Doctor letter and IFU change in Europe. ***How all this plays out is to be determined, but it's clearly going to take some time for clinicians to rethink the role of Nellix, for the FDA to get comfortable with Nellix data, and for investors to reclaim confidence in management and the Endologix story."***
>
> "As a starting point, here is what we know about the Nellix late migration signal thus far: there were a handful of patients in the IDE trial that showed >10, of device migration at 1-year and increasing level of migration at 2-years….On the back of the IFU change and the disclosure of increasing evidence of migration between years 1 and 2, the FDA told Endologix it wants to see the 2 year data. ***Until we see that data, we really don't know how many of these migrations are clinically significant, which is now the #1 question.***
>
> [Emphasis added].

137. A JP Morgan analyst subsequently noted the doubts raised surrounding the problem of Nellix EVAS migration:

> We also don't know at what point the migration stops, if ever, and therefore is 2-year follow-up, the new ask for Nellix, sufficient? If we see evidence of migration out 2-years, even if there's limited evidence of real patient risk from migration, how do we know the FDA will be comfortable approving the

> product, unless it can conclude that the current on-market devices face similar issues? This is the uncertainty today that's facing Nellix.
>
> …While the company looked to be on the cusp of another significant growth phase as it pushed for a 4Q16 approval of its next-gen Nellix device, the announced delays to US launch of Nellix and a label change narrowing its applicability has significantly delayed one of the company's most significant growth drivers. ***While Nellix had the potential to be a disruptive new technology with uptake in Europe presenting a strong case for device adoption, the one-year delay in approval (for an older generation device, no less) was a severe setback for Endologix.*** [Emphasis added].

138. Then, on May 17, 2017 Endologix revealed to investors that after meeting with the FDA it would *not* be seeking approval of the first generation Nellix EVAS System device after all. Instead, it would seek approval of a new second generation or "Gen2" Nellix EVAS device. This would require a completely separate clinical trial, and would push the timeline for approval of Nellix EVAS all the way out to 2020. In a press release entitled "Endologix Provides an Update on the Nellix Endovascular Aneurysm Sealing System U.S. Regulatory Status" Endologix informed investors that it had met with the FDA and that "based upon that meeting and further internal analysis, the company has determined that it will seek U.S. approval of the Nellix EVAS System by conducting a confirmatory clinical study with the previously updated Instructions for Use (IFU) and the Gen2 device design…The Company will collaborate with the FDA over the coming months on the confirmatory clinical study protocol and anticipated beginning patient enrollment in the fourth quarter of this year ***with PMA approval estimated to occur in 2020***. (emphasis added).

139. On this news, Endologix's share price fell over 36% or $2.47 per share from their closing price of $6.73 on May 17, 2017 to close at $4.26 on May 18, 2017.

The stock price decline following this news drove Endologix's share price to fall to its lowest level in six and half years, with analysts downgrading the stock in droves.

140. Analysts reacted stridently to this news. In a May 23, 2016 report a JP Morgan analyst stated: "At Endologix, the final shoe seemed to drop last week…Recent datasets on the base of adverse event signals never work in the pharmaceutical industry and rarely in devices…[ ]***the reason why Nellix won't get approved with the existing data: the FDA doesn't need to approve a device that presents increased risk to patients… At this point investors should take a US approval for Nellix out of their models…The question is now what is Endologix worth without Nellix…*** [Emphasis added].

Materially False and Misleading Statements

141. The Class Period begins on May 5, 2016. By that date, Nellix had been on the market in Europe for approximately three years and three months. The extreme spike in migration, which became readily apparent by the second year of the device being implanted, was well known to Defendants.

142. Additionally, Defendants were required to disclose to the FDA the data, complaints and reports from Europe evidencing migration consistent with the PMA application requirements of 21 C.F.R. 814.20(b)(8)(ii).

143. Presumably, Defendants followed FDA regulations and disclosed the adverse events in Europe to the FDA. If the FDA was not aware of the adverse event reports in Europe that only meant that Defendants intentionally withheld that damning information from the FDA, thereby submitting a materially false PMA, and therefore unapprovable application.

144. While there were less than 500 Nellix devices at issue in the IDE and the Global Registry, by August of 2016 Defendants' *worldwide* experience with

Nellix included over 6,000[14] patients, or 5,500 patients in Europe who had been using Nellix as early as 2013. Accordingly, Defendants' real-world commercial experience with Nellix in Europe overwhelmed the limited data from the IDE Study and Global Registry.

On May 5, 2016 Endologix, represented by Defendant Mahboob, submitted a presentation at the Deutsche Bank Health Care Conference. During the Management Discussion Section Defendant Mahboob discussed FDA approval of the Nellix EVAS System in the U.S.:

> A lot of discussion about FDA approval in the U.S. We published a press release in April that we have submitted all of the four modules at the earnings call in February. We talked about submitting them within 60 days to 90 days after the earnings call. We're happy to report that we've submitted all the four modules to the FDA, they have them. And we have to wait for a 45-day period for the FDA to say that submission is complete, and then the 180-day window starts. And if you take that and say that and say 180 days ***gets you to the October-November time, that's what we've been saying consistently***.
>
> I get a lot of questions about the panel, and John and our position is that there is nothing in the data that we see today that leads us to believe, but there will be a panel. But at the end of the day, this is the first PMA approval for EVAS versus EVAR and the agency will do what they have to. ***But today, we feel pretty good about the timeline that we've been putting out consistently for the last six months to eight months, which is that we expect the approval to be in the Q4 [2016] to latest Q1 [2017] timeframe.*** The one big piece of data is going to be presented at SVS, which is on June 11 here in Boston, is the data

[14] *See* Endologix August 2, 2016 Form 8-K.

for the IDE clinical data, which is going to be presented. And that's going to happen in June. ***So again, on track from a PMA milestone for a Q4 approval.***

]Emphasis added].

145. The above statement by Defendant Mahboob was materially false and misleading and/or omitted material information because Defendant Mahboob had actual knowledge that the Nellix EVAS System was not on track for Q4 2016 FDA approval due to the severe, consistent and unresolved problems with the Nellix EVAS System and migration which rendered the device, in its current state, unsafe because of the unacceptable safety risks device migration posed, thereby preventing FDA approval according to the timeline Defendants were "putting out consistently." By stating that Endologix was "on track" with its timeline for FDA approval in "Q4 2016 to latest Q1 2017 timeframe" Mahboob falsely conveyed to investors that there was nothing standing in the way of FDA approval of Nellix. In representing that it was even possible for the then-current version of Nellix to be approved, Mahboob impliedly represented that it was "safe and effective" for its intended use, a prerequisite for FDA PMA approval. Given the abundance of evidence concerning migrations, Mahboob knew that Nellix was not safe, and would not receive FDA PMA approval. At the very least, the evidence from Europe regarding migration was required to be disclosed to investors in order to make Mahboob's positive statements about Nellix's anticipated FDA approval not misleading.

146. On May 9, 2016, Endologix issued a Press Release filed with the SEC on Form 8-K, preliminarily announcing its financial results for the three months ended March 31, 2016 ("1Q 2016"). In the 1Q 2016 Press Release Defendant McDermott stated: "For Nellix…we remain on track with our timeline for potential FDA approval at the end of 2016 or early 2017."

147. The above statement by Defendant McDermott in the 1Q 2016 Press Release was materially false and misleading and/or omitted material information because McDermott had actual knowledge that the Nellix EVAS System could not receive FDA approval at the end of 2016 or early 2017 due to the severe, consistent and unresolved problem of migration with the Nellix EVAS System, which rendered the device, in its current state, unsafe because of the unacceptable safety risks device migration posed. By stating that Endologix was "on track" with its timeline for FDA approval McDermott falsely conveyed to investors that there was nothing standing in the way of FDA approval of Nellix. In representing that it was even possible for the then-current version of Nellix to be approved, McDermott impliedly represented that it was "safe and effective" for its intended use, a prerequisite for FDA PMA approval. Given the abundance of evidence concerning migrations in Europe and elsewhere, McDermott knew that Nellix was not safe, and the FDA would not approve it. At the very least, the evidence from Europe regarding migration was required to be disclosed in order to make Defendants' positive statements about Nellix's safety and anticipated FDA approval not misleading.

148. Also on May 9, 2016 Endologix held its 1Q 2016 conference call with investors. During the call an analyst asked Defendant Mahboob about how Nellix was performing overall: "I'm hoping you can give us a feel for the underlying Nellix or I guess Nellix in the direct channel…is Nellix kind of on the same trajectory that we have been seeing over the last couple of quarters[?]." Defendant Mahboob responded, stating, in part "Nellix continues to do a fantastic performance outside of the U.S. […] So I would say, Nellix is doing as expected. No surprises."

149. The above statement by Defendant Mahboob was materially false and misleading and/or omitted material information because Defendant Mahboob had actual knowledge that Nellix was ***not*** doing a "fantastic performance outside of the U.S." or doing "as expected" because Mahboob knew that Endologix was being

deluged with complaints from European physicians about Nellix and migration, and Endologix's own scientists had told management that this was a serious problem that could not be resolved or explained. At the very least, the evidence from Europe regarding migration causing adverse events and endangering patients was required to be disclosed in order to make Defendants' positive statements about Nellix's performance outside of the U.S. not misleading. Moreover, the huge number of adverse events from Nellix migration in Europe was a red flag for investors indicating that the FDA would not approve Nellix once it learned that it was prone to migration after a year from implantation. Thus, this false statement compounded and supported Defendants' false statements that Nellix was on track for FDA approval in the fourth quarter of 2016.

150. Additionally, on the May 9, 2016 conference call Defendant McDermott responded to an analyst's request to provide follow up on the FDA process, stating in part: "At this point, I can tell you the process is clicking ahead on schedule and the interaction with the FDA has been constructive. So right now everything continues to look like a PMA approval, hopefully, by the end of this year or the first part of next year."

151. The above statement by Defendant McDermott was materially false and misleading and/or omitted material information because Defendant McDermott knew that there was absolutely no hope of receiving FDA PMA approval by the end of 2016 or the first part of 2017 due to the severe, consistent and unresolved problem with the Nellix EVAS System and migration which made the Nellix EVAS System, in its current form unsafe and therefore the FDA would not approve it for use in the U.S. because of the unacceptable safety risks device migration posed. In representing that it was even possible for the then-current version of Nellix to be approved, McDermott impliedly represented that it was "safe and effective" for its intended use, a prerequisite for FDA PMA approval. Presumably, Defendants followed the

requirements of 21 C.F.R. 814.20(b)(8)(ii) and did in fact submit to the FDA the data concerning the huge number of adverse events and complications with the Nellix EVAS System as well as any patient or doctor complaints that occurred in Europe. In the alternative, if Defendants did not do so they intentionally and illegally lied to the FDA by withholding information legally required to be disclosed, thereby submitting a false PMA application. At the very least, the evidence from Europe regarding migration was required to be disclosed in order to make Defendants' positive statements about Nellix's safety and approvability not misleading.

152. Then, on August 2, 2016, with anticipated FDA approval nearing closer, the Company held a conference call with investors to discuss the Company's financial results for the quarter ended June 30, 2016 (the "Q2 2016 Conference Call"). During the Q2 2016 Conference Call, Defendant McDermott stated that "we remain very positive about the likelihood of approval [for Nellix EVAS System] and the significant growth we expect to drive with Nellix."

153. In reporting its results for Q2 2016 on August 2, Endologix acknowledged the relevance and consideration by the FDA of the commercial experience with patients in Europe in its quest for PMA approval stating "we are working very collaboratively with the FDA to provide the required information and remain confident in the PMA approval of Nellix based upon the IDE clinical results, data from other international studies ***and our worldwide experience which now includes over 6,000 patients***." (emphasis added).

154. During the Q2 2016 Conference call, Defendant McDermott further assured investors that no issues exist with the data from the IDE Study, stating in pertinent part:

> **Matt Blackman**
> Okay, that's very helpful. And I'm going flip in one last question back on the panel. I'm sure you're eager to provide the intimate details of your FDA discussions…But maybe give us a little bit more color,

> more sense of comfort that there is not something else going on, there is no sort of red flag raised in terms of data that they saw. I guess, anything that you could give us that, gives us any comfort there would be helpful? Thank you.
>
> **John McDermott**
> Sure. So, the three reasons that the agency will typically consider sending a device to panel is one; if there is, any new clinical issues of safety efficacy and obviously **everyone has seen the data so we know there aren't any issues there.** The second reason is if they feel - the FDA feels they don't have the clinical or technical expertise to complete the review of a PMA, that's not the case. So and the third is if it's novel technology.
>
> [Emphasis added].

155. Additionally, during the Q2 2016 Conference call, Defendant McDermott indicated that none of the questions the FDA posed to the Company suggested there was any risk the FDA would not approve the device, stating in pertinent part:

> **Joanne Wuensch**
> Hi. Can we talk a little bit about what type of additional data or questions that you're receiving? I mean, is there any way to give us some information regarding that?
>
> **John McDermott**
> Yes, I don't want to get too detailed with that Joanne. What I can tell you, is that **none of the questions we got asked are what I would characterize as big surprises**. There is clarification on some things, some requests for additional analysis, some additional testing. **Nothing that would suggest in our view any question or risk of approvability, just some more blocking and tackling and clarification of the data we submitted**.
>
> **So, we don't see anything in there that's given us heartburn**. It will just take a little time to pull it altogether. And we'd also like to

> take another run at this novelty question and see if we can provide the agency with enough evidence that the device isn't novel so that we don't have to go to panel. So that would be the focus of the work we do over the next few months.
>
> [Emphasis added].

156. The statements in ¶¶152-155 above were materially false and misleading and/or omitted material information because Defendants had actual knowledge that: (1) not only was it unlikely that the Nellix EVAS System would receive FDA approval in the U.S. consistent with the timeline Defendants were putting out to investors, it was impossible, given the severe, consistent and unresolved problem with the Nellix EVAS System and migration which made the Nellix EVAS System in its current form unapprovable in the U.S. because of the unacceptable safety risks device migration posed; (2) there were in fact serious "issues with the data" such that Endologix had in its possession an abundance of clinical data, including in the Company's complaint database and clinical trial database which Defendants were well aware of, and which Defendants were required to disclose to the FDA, that demonstrated the severe and intractable problem of migration that made the Nellix EVAS System, in its current form, unapprovable in the U.S. because of the unacceptable safety risks device migration posed; and (3) the evidence from Europe concerning migration that Defendants were required to submit to the FDA did in fact create 'issues with the data" as it demonstrated that the Nellix device, in its current form was unsafe due to migration and could not be approved.

157. Defendants admitted on the August 2, 2016 conference call that they followed the requirements of 21 C.F.R. 814.20(b)(8)(ii) and did in fact submit to the FDA the adverse events and complications with the Nellix EVAS System as well as any patient or doctor complaints that occurred in Europe. In the alternative, if Defendants did not do so they intentionally and illegally lied to the FDA by

withholding information legally required to be disclosed, thereby submitting a false PMA application. At the very least, the evidence from Europe regarding migration was required to be disclosed in order to make Defendants' positive statements about Nellix's safety and approvability not misleading.

158. On November 1, 2016, during aftermarket hours, the Company held a conference call with investors to discuss the Company's financial results for the quarter ended September 30, 2016 (the "Q3 2016 Conference Call"). During the Q3 2016 Conference Call, Defendant McDermott touted the Company's positive interaction with the FDA, stating in pertinent part:

> **John McDermott**
> In terms of the U.S. PMA, we achieved the clinical endpoints in the IDE share dilated clinical data with FDA. We've also provided them with our updated patient selection criteria and ***have had positive discussion so far. Nellix PMA approval time lines are unchanged although we think a panel is more likely now given the updated indications.***

[Emphasis added].

159. The issue of migration and Nellix EVAS System came up on the Q3 2016 Conference Call, with Defendants telling investors that the FDA requested that Endologix submit "the most recent cut of the data for them to review," and that Endologix had changed the Indication For Use ("IFU") for Nellix EVAS based upon the "updated data cut" that Endologix had recently run. Defendant McDermott stated:

> Regarding Nellix, ***we've recently ran an updated data cut from the IDE clinical database and noticed an increase in migration in aneurysm enlargement in some patients with two-year follow-up***. We've learning that migration can occur in patients with small flow lumens ***and a lot of thrombus*** because there isn't enough space to inject sufficient polymer

> to support the stents. ***Our solution is a simple update to the patient's selection criteria*** that measures the ratio of aneurysm diameter to the flow lumen to ensure there is enough space for polymer…When we examined the IDE data for patients that fit within this updated selection criteria, ***we see extremely positive safety and durability results out to two years***, which gives us confidence that Nellix can be a leading device in the treatment of abdominal aortic aneurysms.
>
> (Emphasis added)

160. On the Q3 2016 Conference Call Defendant McDermott portrayed migration of the Nellix EVAS System as only recently coming to Defendants' attention and went on to emphasize Endologix's favorable interactions with the FDA, reassuring investors that any concerns related to migration were minimal stating: "we did have a successful clinical study and met the endpoints in the trial. So actually when we interacted with the agency so far on the updated indications, they've responded favorably. ***They had some questions about migration and a curiosity if it was progressive…we really can't get into any of the data details as this point in time…But what I can tell you is that the re-interventions related to this issue are extremely low***." (Emphasis added).

161. McDermott also emphasized that the issue of migration was "***a very easy situation*** to address just by narrowing for those particular anatomies" adding that "I think people are – have given us a lot of credit for being so proactive and getting out ahead of it. We'll say there are some physicians who think we're being a little conservative, but our view is let's be- let's think patient safety first and then we can see some ways to open up this patient criteria moving forward." (Emphasis added).

162. Defendant McDermott's above statements on the Q3 2016 Conference Call were materially false and misleading and/or omitted material information because: (1) the Nellix EVAS System timeline for FDA approval was not "unchanged" because the severe, consistent and unresolved problem with the Nellix

EVAS System and migration causing unacceptable safety risks meant that the FDA would not approve the Nellix EVAS System in accordance with the timeline Defendants had been putting out to investors; (2) Defendants did not recently learn about the high incidence of migration with the Nellix EVAS System when it ran an "updated data cut"- in reality Defendants were well aware of the frequency of device migration with Nellix, a phenomenon that continually increased since at least the beginning of 2015 and that had sparked Endologix's senior executive to pressure McDermott to issue a field safety notice and narrow Nellix's IFU in November 2015; (3) Defendants were aware, at least one year prior, that they should narrow the IFU to exclude patients with a lot of thrombus but refused to do so; and (4) migration of the Nellix EVAS System was not "a very easy situation to address-" to the contrary, it had plagued the Individual Defendants and the Company's scientists who were not only unable find a solution to the migration problem, but could not even figure out what was causing the devices to migrate in the first place.

163. Additionally, the above November 1, 2016 statements were misleading in context because McDermott omitted that Endologix had been searching for a solution to the migration problem since 2015 and that McDermott even personally created and oversaw an Endologix "task force" to investigate the migration issue in January 2016. At the very least, the evidence from Europe regarding migration was required to be disclosed in order to make Defendants' positive statements about Nellix's safety and anticipated FDA approval not misleading.

164. On November 16, 2016, before market open, Endologix issued a press release entitled "Endologix Provides Update on Nellix PMA Process," revealing that Nellix EVAS would not receive FDA approval consistent with the "timeline" that the Company had promised investors. Instead, the FDA had requested that the Company provide 2-year patient follow-up data from the Nellix EVAS Forward IDE Study. According to the Company this would mean that FDA PMA approval of Nellix could

not occur until the second quarter of 2018, delaying approval at least an additional 18 months based upon the planned 4th quarter 2016 approval the Company had previously announced. McDermott stated: "we're disappointed by these requirements and the resulting delay, but encouraged by the 2-year clinical outcomes we have seen so far with Nellix under the newly revised instructions for use. We remain committed to EVAS and Nellix and have demonstrated outstanding clinical results in selected patients with both traditional and complex AAA anatomies."

165. In reality, this was no surprise to Defendants. By early 2015 marketing of Nellix in Europe had been going on for two full years. Defendants knew from their experience in Europe that it was between years 1 and 2 of implantation with Nellix that device migrations began to occur. By February 2016, the IDE Study and Global Registry had been going on for two years and Defendants would have identified the same problem with migration in the clinical trials that was occurring in Europe.

166. On November 17, 2016 Endologix held its 2016 Investor Meeting. McDermott responded to an analyst's question and presented as new information what Defendants had known and hid from investors all along: that there was a problem with Nellix EVAS System and migration endangering patients' lives and that as a result the FDA required additional data to determine the real patient risk from migration before it could consider approving the device:

> Analyst:
>
> …were there migration issues in that subset of patients that the FDA already saw and is that why they're saying give me the two years for everybody?
>
> John McDermott:
>
> Yes. So everybody saw the one-year data which was 2.3% of patients had a 10 millimeter migration or more at one year. What we saw was when we did an updated data cut for our response, some of those patients

> went on to migrate more and there were some patients ***that hadn't displayed any migration at one year that showed signs of migration in year two.***
>
> And although most of those findings still hadn't triggered interventions, there were some and I'm not going to tell you there were zero intervention. I honestly, right now, don't know the exact number off the top of my head, but it was really the change in the rate. It was the increase in the rate from year one to year two and that's what drove the discussion.

(emphasis added)

167. The above statement was false and misleading and/or omitted material information in presenting as new information to investors what Defendants had known and hid all along: that the evidence of migration from the data the FDA saw resulted in the FDA requiring additional clinical data to determine the real patient risk from migration. As Defendant McDermott stated "it was the increase in the rate from year one to year two." *Id.* As in Europe, where Nellix had good results in the clinical trials early on and migration did not occur until Nellix had been implanted for about a year. But Defendants knew that in early 2015, based on their experience marketing Nellix in Europe.

POST CLASS PERIOD EVENTS

168. In the Company's Form 10-Q for the second quarter of 2017 filed with the SEC on August 4, 2017 the Company announced that it was being investigated by the SEC concerning the Nellix EVAS System, stating that "In July 2017, the Company learned that the United States Securities and Exchange Commission (SEC) has issued a Formal Order of Investigation to investigate, among other things, events surrounding the Nellix EVAS System and the prospect of its FDA pre-market approval."

169. A week later, on August 10, 2017, the Company's Vice President of Regulatory Affairs notified the Company of her intention to resign effective September 8, 2017.

170. Presentations concerning the Nellix EVAS System after the Class Period confirm what Defendants knew since the beginning of 2015: that Nellix began to migrate between one and two years following implantation and that the IFU for Nellix needed to be narrowed thereby drastically reducing its commercial appeal. For example, in a presentation by Matt Thompson, Endologix's Chief Medical Officer entitled "Nellix: Lessons Learned after 3 Years and Potential for Future Development" one slide is aptly titled "3 Years of EVAS- the story so far "***failure modes apparent at 2y. Migration.***[15] (Emphasis added)."

171. Another presentation by John Lane, Acting Chief of Vascular Surgery at the University of California, San Diego and a consultant for Endologix noted "reduced applicability" given the refinement of the IFU "EVAS performs best in AAA with low thrombus burden…***migration signal at 2 years in AAA with large thrombus burden***. (emphasis added)[16]"

ADDITIONAL SCIENTER ALLEGATIONS

172. The fraud alleged herein involved the Company's core operations, as Defendants repeatedly emphasized the primacy of the Nellix EVAS System and its

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[15] Available at http://webcache.googleusercontent.com/search?q=cache:dwTaOnuFY3YJ:www.cong-o.de/index.php%3Foption%3Dcom_docman%26task%3Ddoc_download%26gid%3D467+&cd=14&hl=en&ct=clnk&gl=us

[16] Available at: http://pnec-seattle.org/images/2NellixLanePNEC.pdf

role as the driver of the Company's future growth. Since Endologix's success and future prospects depended on U.S. approval of the Nellix EVAS System, Defendants had the motive to mislead the market about the prospects of the Nellix EVAS System given that the Nellix EVAS System was "the biggest thing the Company had."

173. As CEO and CFO, McDermott and Mahboob were responsible for preparing and delivering investor presentations to analysts and investors.

174. Defendants McDermott and Mahboob personally received weekly and at times daily briefings about the increasing number of complaints from doctors and patients in Europe about migration of the Nellix EVAS System in patients. In particular, CW1, who was the Head of Aortic Procedure Development working directly on Nellix stated that McDermott personally created and oversaw an Endologix "task force" to investigate the migration problem in January 2016.

175. Defendant McDermott was personally urged by CW1 and other high-level Company officials, including the Vice President of Quality (Jose Lima), the Vice President of Clinical Affairs (Chuck Love), the Senior Director of Global Clinical Affairs (Avyaya Sharma) and the Thoracic Therapies Business Leader (Afir Iftekhar) in March of 2016 to change the indications for use and issue field safety notices to doctors regarding the problems of migration and refused to do so until the FDA brought up the issue of migration nearly one year later. Defendant McDermott also personally approved the Company's presentation on Nellix and migration given at the March 2016 Symposium on Aneurysm Sealing in London.

176. Defendants McDermott and Mahboob not only had access to and were aware of the Company's complaint database and clinical trial database which detailed the reports of migration of the Nellix EVAS System, they were also "***given everything***" generated in "endless meetings analyzing every data point from every patient," including the "thousands of pages of paper with studies and reports"

concerning migration and Nellix" during the period from the beginning of 2015 to at least June 2016.

177. Defendants' motivation to bring the Nellix EVAS system to market quickly, despite their full knowledge of associated risks to patients' lives, also supports an inference of scienter. Here, the successful development of a rival EVAS system by competitors was seen as a competitive threat and a major risk to Endologix by analysts and investors.

178. The impact of the revised IFU on Nellix's sales prospects also supports an inference of scienter. The narrowed IFU resulted in a much smaller market for Nellix and in turn diminished anticipated revenues from Nellix by at least 37% annually and diminished Endologix's overall expected future revenue by at least 14%. This revenue decrease (once disclosed publicly) would therefore decrease the expected future value of cash flows, and hence decrease the current market price of Endologix stock.

179. For example, 37% of all patients treated in the Global Registry had complex anatomies outside of the IFU[17] meaning that of the 300 patients in the Global Registry, 111 of them would not be able to use Nellix.

180. One presentation at a conference in the Netherlands from December 7-9 2017 stated that ""Mid-term results of 300+ patients treated by endovascular aortic sealing (EVAS) dated Dec 7-9th noted that in a study of 355 patients 64% of them were within the old IFU whereas only 18% of those 355 patients were within the

[17] *See* "Practicing Outside of the IFU- Also an Issue With New Sac Filling Technologies," Matt Thompson, available at https://linc2017.cncptdlx.com/media/0944_Matt_Thompson_25_01_2017_Room_2_-_Main_Arena_2.pdf

refined IFU." Importantly, the presentation noted that "***the refined IFU significantly reduced the applicability of the technique***".[18]

181. The appeal of Nellix to the market and investors was not only that it was the first device of its kind it was also the broad applicability for use in all AAA patients that Defendants touted. Revising the IFU significantly undermined that.

182. Revising the IFU also contributed to an overall reduction of the Company's revenues. For example, in the Company's 10-Q for the quarterly period ended September 30, 2017 the Company noted the decline in overall European sales driven by the reduction in revenue from Nellix because of the refined IFU: "Net sales of products in our international regions totaled $15.1 million in the three months ended September 30, 2017, a 4.5% decrease from $15.8 million in net sales of products in our international regions in the three months ended September 30, 2016. Both AFX and Ovation product lines posted strong growth ***which was offset by a decline in Nellix sales reflecting the narrowed IFU.***" (Emphasis added).

183. In addition, revising the IFU would result in a major delay in FDA approval. Because revising the IFU would eliminate patients already in the IDE Study and Global Registry the FDA would require additional patient enrollment to make up for the reduction in patients excluded because of the narrowed IFU. For example, because the refined IFU resulted in the exclusion of 111 patients from the Global Registry Endologix would have to enroll an additional 111 patients in the Global Registry and study them for two years. If Defendants refined the IFU in November 2015 and enrolled new patients by January 2016 study results would not

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[18] *See* Mid-term results of 300+ patients treated by endovascular aortic sealing (EVAS), Jean-Paul P.M. de Vries, 7th MAC Conference Munchen, Dec 7-9th 2017. Available at http://mac-conference.com/wp-content/uploads/2017/12/02_DEVASS.pdf

be complete until January 2018, and PMA approval could not occur until the first or second quarter of 2018- at least 15 months later than the fourth quarter 2016 estimate of PMA approval Defendants held out to investors during the Class Period.

184. Accordingly, despite knowing for at least one full year that a revised IFU was necessary to prevent serious adverse events that could result in death, Defendants held off in revising the IFU for as long as possible putting patients' lives at risk.

185. Additionally, the SEC's investigation of Endologix concerning the events surrounding the Nellix EVAS System and the prospect of its FDA pre-market approval which was announced after the close of the Class Period supports an inference of scienter.

LOSS CAUSATION

186. During the Class Period, as detailed herein, Defendants made false and misleading statements and omitted material information concerning the prospects for FDA approval of the Nellix EVAS System's prospects for FDA approval, and engaged in a scheme to deceive the market. Defendants knowingly misstated and omitted material information concerning the approvability of the Nellix EVAS System by the FDA in order to improve the market's perception of Endologix's worth, causing Endologix to trade at artificially inflated prices.

187. By artificially inflating Endologix's stock price, Defendants deceived Plaintiff and the Class and caused them losses when the truth was revealed. When Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, Endologix's share prices fell precipitously as the prior artificial inflation came out of the price. Endologix's share price fell $2.02 per share on November 16, 2016, or over 20.5% when the Company announced the FDA would require another two years of safety data due to the safety threat posed by migration of Nellix. Then on May 17, 2017 Endologix's share price dropped $2.47 per share of 36% when the

Company announced that it would *not* seek approval of the first generation Nellix EVAS System device after all because of the intractable problems with migration. Instead, Endologix would seek approval of a second generation or "Gen2" Nellix EVAS device.

188. As a result of their purchases of Endologix securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

189. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Endologix securities publicly traded on the NASDAQ during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

190. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Endologix securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

191. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

192. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

193. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- whether the prices of Endologix securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

194. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

APPLICABILITY OF PRESUMPTION OF RELIANCE: AFFILIATED UTE

195. Neither Plaintiff nor the Class need prove reliance – either individually or as a class – because under the circumstances of this case, which involve omissions of material fact as described above, positive proof of reliance is not a prerequisite to recovery, pursuant to the ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 1456, 31 L. Ed. 2d 741 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

FRAUD-ON-THE-MARKET DOCTRINE

196. Plaintiff will rely upon the presumption of reliance established by the fraud on the market doctrine in that, among other things:

197. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

198. The omissions and misrepresentations were material;

199. The Company's stock traded in an efficient market;

200. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

201. Plaintiff and other members of the Class purchased Endologix common stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

202. At all relevant times, the market for Endologix common stock was efficient for the following reasons, among others:

203. As a regulated issuer, Endologix filed periodic public reports with the SEC. Endologix met the requirements for listing, and was actively traded on the NASDAQ, under ticker ELGX;

204. On May 5, 2016, there were 81.819 million Endologix shares outstanding;

205. During the Class Period, an average of 7,849,385 Endologix shares were traded weekly, or about 9.6% of Endologix's total shares outstanding;

206. Endologix regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services.

207. Endologix was eligible to file short-form registration statements with the SEC on Form S-3;

208. Endologix was followed by numerous analysts that issued reports about it.

209. New company specific information was rapidly reflected in the Company's stock price.

NO SAFE HARBOR

210. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Endologix who knew that the statement was false when made.

211.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5

Against All Defendants

212. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

213. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

214. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were

misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

215. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Endologix securities during the Class Period.

216. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

217. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth

when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

218. As a result of the foregoing, the market price of Endologix securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Endologix securities during the Class Period in purchasing Endologix securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

219. Had Plaintiff and the other members of the Class been aware that the market price of Endologix securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased Endologix securities at the artificially inflated prices that they did, or at all.

220. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

221. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of Endologix securities during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act

Against The Individual Defendants

222. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

223. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

224. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

225. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Endologix securities.

226. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the

power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

227. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: January 9, 2018

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

By: Laurence M. Rosen, Esq.
Laurence M. Rosen, Esq. (SBN 219683)
355 S. Grand Avenue, Suite 2450
Los Angeles, CA 90071
Telephone: (213) 785-2610
Facsimile: (213) 226-4684
Email: lrosen@rosenlegal.com

Sara Fuks, Esq. (admitted *pro hac vice*)
275 Madison Avenue, 34th Floor
New York, NY 10016
Telephone: (212) 686-1060
Email: sfuks@rosenlegal.com

Lead Counsel for Lead Plaintiff