UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

BARBARA JARRETT, *Plaintiff*, v. ABBOTT LABORATORIES; BOSTON SCIENTIFIC CORPORATION; BOSTON SCIENTIFIC NEUROMODULATION CORPORATION, *Defendants*.	Case No. **COMPLAINT FOR DAMAGES AND DECLARATORY AND INJUNCTIVE RELIEF** **JURY TRIAL DEMANDED**

Plaintiff BARBARA JARRETT ("Plaintiff") by and through undersigned counsel, and for their Complaint against Defendants ABBOTT LABORATORIES, BOSTON SCIENTIFIC CORPORATION, and BOSTON SCIENTIFIC NEUROMODULATION CORPORATION seeking damages (the "Action") as follows:

INTRODUCTION

This is a product liability action involving injuries sustained by Plaintiff following the implantation and failure of a spinal cord stimulator (SCS) system designed, manufactured, and marketed by Defendant Abbott Laboratories ("Abbott"), as well as Defendants Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, "Boston Scientific"). The devices were implanted in Plaintiff's body as a purported treatment for chronic pain, but they failed to perform as promised and instead caused serious harm.

The SCS devices at issue received Food and Drug Administration ("FDA") approval under original PMAs. Since that time, however, the devices have been fundamentally altered through hundreds of PMA supplements, modifying their battery chemistry, firmware, waveform control, leads, and user interface, without the benefit of a new PMA or any renewed clinical safety validation.

These cumulative changes, approved outside public view, transformed the device's mechanism of action, performance characteristics, and risk profile. Abbott and Boston Scientific failed to disclose these material changes to patients, physicians, or regulators. As a result, Plaintiff was implanted with a device that was materially different from what had been tested and originally approved by the FDA. Plaintiff suffered painful symptoms, worsening pain symptoms, and permanent injuries as a result.

Plaintiff brings this Action under California, Florida, Indiana, North Carolina, and/or Illinois law, asserting both traditional product liability and statutory claims. Plaintiff seeks compensatory damages for her injuries.

PARTIES

I. Plaintiffs

1. **Plaintiff** Barbara Jarrett is a citizen of the State of Florida, and a resident of Bay County, Florida, a county in this District. At the time this Complaint is filed, Plaintiff resides in Florida. The devices at issue were implanted in Plaintiff in Indiana and North Carolina. Plaintiff has received medical treatment related to the devices in Indiana, North Carolina, and Florida. Plaintiff had her Boston Scientific SCS devices implanted in 2013 and 2021, respectively, and her Abbott SCS device implanted in August 2021. Plaintiffs final device was explanted in Florida, and Plaintiff has suffered permanent injuries as a result of the implantation and subsequent explantation of these devices.

II. Defendants

2. **Defendant** Abbott Laboratories is a corporation organized under the laws of the State of Illinois with its principal place of business located in Abbott Park, Lake County, Illinois. Abbott Laboratories is a global healthcare corporation engaged in the design, manufacture, promotion, and sale of medical devices, including spinal cord stimulation systems, throughout the United States and within this District. Abbott Laboratories assumed ownership of the SCS device portfolio at issue following its acquisition of St. Jude Medical in 2017.

3. **Defendant** Boston Scientific Corporation is a corporation organized under the laws of the State of Delaware with its principal place of business located in Marlborough, Massachusetts. Boston Scientific is registered and interacts with the Food and Drug Administration through its offices located at 25155 Rye Canyon Loop, Valencia, California 91355. Boston Scientific conducts business nationwide and within this District.

4. **Defendant** Boston Scientific Neuromodulation Corporation is a corporation organized under the laws of the State of Delaware, with its stated principal place of business located in Marlborough, Massachusetts. However, its registered agents and listed authorized employees and functional principal place of business is actually 2710 Gateway Oaks Drive, Sacramento, California. In addition, Defendant Boston Scientific Neuromodulation is registered with the FDA as the Specification Developer for the Boston Scientific device at issue in this complaint, and other similar devices through its facilities located at 25155 Rye Canyon Loop, Valencia, CA 91355. As the Specification Developer for the device at issue in this case, Boston Scientific Neuromodulation was responsible for the development and design of the device at issue, including crucial functions such as design validation, gap analysis, and coordination of Corrective and Preventive Actions ("CAPAs") required by the Food, Drug & Cosmetic Act. Boston Scientific Neuromodulation conducts business nationwide and within this District.

JURISDICTION AND VENUE

5. *Subject Matter Jurisdiction.* This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because the matter in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different states – specifically, Plaintiff is domiciled in Florida, whereas Defendant Abbott Laboratories is an Illinois corporation with its principal place of business located in Illinois, and Defendant Boston Scientific is a Delaware corporation with its functional place of business located in California.

6. *Personal Jurisdiction.* This Court has personal jurisdiction over Defendants Boston Scientific and Abbott Laboratories because they both conduct substantial business within this District, and have purposefully availed themselves of the privileges of conducting activities

within the State of Florida by maintaining sales representatives in the State, marketing their devices in the State, and causing injuries in the State as a result of the implantation of their devices in the State, and have caused harm to Plaintiff who resides in the State.

7. *Venue.* Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred here, including injuries to Plaintiff.

FACTUAL ALLEGATIONS

III. APPLICABLE LAW AND CHOICE OF LAW

8. This Action arises under both state law. Plaintiff brings state-law claims against Abbott and Boston Scientific for personal injuries sustained as a result of its defective spinal cord stimulator system.

9. Plaintiff was implanted and explanted with the Boston Scientific devices in the State of Indiana, was implanted with the Abbott SCS device in North Carolina, currently resides in Florida, had her Abbott SCS device explanted in Florida, and experienced the injuries giving rise to this lawsuit in Indiana, North Carolina, and Florida, and continues to suffer injuries in Florida.

10. However, significant aspects of the design, manufacture, regulatory strategy, and labeling of the device occurred within the States of Illinois and California.

11. Florida, Indiana, and North Carolina law governs Plaintiff's personal injury claim, however, to the extent this action concerns Abbott and Boston Scientific's regulatory decisions, FDA submissions, and corporate conduct occurring in Illinois and California, Plaintiff invoke Illinois and California law in the alternative for claims that arise from Defendants' forum-based behavior.

12. Plaintiff does not, at this time, choose a specific law, but rather, pleads the laws of the several states above in the alternative subject to the Court's decision on choice of law.

IV. REGULATORY BACKGROUND AND PMA HISTORY

13. SCS devices are Class III implantable neuromodulation systems designed to deliver electrical impulses to the spinal cord to mask or modulate chronic intractable pain. SCS systems typically consist of an implantable pulse generator (IPG), one or more electrical leads, and external patient controllers for adjusting therapeutic levels.

14. The underlying therapeutic premise of SCS devices is that electrical stimulation of the dorsal columns can "override" or "mask" the transmission of pain signals to the brain, thereby providing relief for chronic pain conditions that are otherwise resistant to conventional treatments.

15. SCS devices have long been associated with complex risks, including but not limited to device migration, lead breakage, battery failure, infection, stimulation-induced neurological deficits, exacerbation of pain, and autonomic dysfunction.

16. Due to these inherent risks, SCS devices are classified by the FDA as Class III medical devices. The federal regulatory framework is referenced solely to describe the type of safety information ordinarily available to manufacturers of implantable medical devices and relied upon by physicians when making treatment decisions, and not as an independent basis for liability.

17. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., requires that all Class III medical devices undergo pre-market approval ("PMA") by the United States Food and Drug Administration ("FDA") before they may be introduced into interstate commerce. The PMA process is the most rigorous pathway under the FDCA and is intended to ensure the safety and effectiveness of devices that support or sustain human life, prevent impairment of human health, or present a potential unreasonable risk of illness or injury.

18. Once a PMA is approved, 21 C.F.R. § 814.39(a) prohibits any change to the design, materials, energy source, software, manufacturing process, or labeling of the device that could significantly affect its safety or effectiveness without submission of a new PMA or a panel-track PMA supplement. The manufacturer bears the burden of demonstrating continued safety

and effectiveness for all significant changes. Manufacturers may not use the PMA supplement process as a backdoor to avoid new clinical testing or public review.

19. The Abbott spinal cord stimulator (SCS) systems were marketed under original PMA P010032, originally approved in 2001 for a basic neurostimulator system manufactured by Advanced Neuromodulation Systems, Inc. This predicate device consisted of an implantable pulse generator (IPG), fixed stimulation output parameters, a wired programming system, and a battery designed for limited-term use. This predicate system was called the Genesis Neurostimulation (IPG) System.

20. Since that time, Abbott has submitted more than 200 PMA supplements, fundamentally transforming the device's internal firmware, waveform architecture, patient interface, battery design, wireless communication, and safety-critical stimulation parameters. Despite these cumulative changes, no new PMA has ever been required or submitted.

21. Upon information and belief, the following PMA supplements illustrate material modifications that independently or cumulatively significantly altered the Abbott device's safety and effectiveness:

Supplement #	Decision Date	Supplement Type	Device/Model	Description / Relevance
S025	01/29/2009	Real-Time Process	Genesis RC & Eon	Design/components/specification change
S028	03/19/2009	180-Day Track	Eon Mini	Manufacturer/location change
S058	09/14/2012	Real-Time Process	Eon Mini	Design/components/specification change
S066	03/15/2013	Real-Time Process	Eon Mini	Design/components/specification change
S068	05/17/2013	Real-Time Process	Eon Mini 2.0	Design/components/specification change
S073	04/25/2014	180-Day Track	Eon Mini	Manufacturer/location change
S086	11/13/2014	30-day notice	Eon Mini / Protégé / Protégé MRI	Platform/device family expansion

BurstDR Approval	10/2016	Approval	Prodigy / Proclaim Elite	BurstDR therapy approval (new stimulation pattern)
S125	07/21/2017	180-Day Track	Proclaim IPG Family	Platform evolution, new device family approval
S151	09/09/2019	Real-Time Process	Proclaim SCS Family	Labeling change (indications, trade name)
Proclaim XR Launch	09/26/2019	Press Release	Proclaim XR	Recharge-free, low-dose BurstDR launch
S167	08/18/2020	Real-Time Process	SCS IPG	Design/components/specification change
S187	08/19/2022	Real-Time Process	Proclaim SCS	Design/components/specification change
S189	01/24/2023	Panel Track	Prodigy / Proclaim / Proclaim XR	Indication expansion (e.g., DPN)
S213	06/26/2024	180-Day Track	SCS IPG Family	Design/components/specification change

22. These changes cumulatively altered the device's mode of action, safety controls, stimulation effects, battery stability, and susceptibility to failure. Abbott did not conduct new clinical trials to validate these design changes and failed to disclose material risks to physicians and patients, including Plaintiff.

23. On September 11, 2023, the FDA classified five separate Class I recalls of Abbott's Proclaim-series SCS devices, including the Proclaim DRG IPG, XR 5/7 IPGs, and Plus 5/7 IPGs. These recalls were issued in response to complaints from patients experiencing painful electric shocks, sudden device shutdowns, and failure to deliver therapeutic stimulation. These hazards arose from the very firmware, waveform, and interface changes introduced by the above-listed supplements.

24. On May 16, 2024, Abbott initiated a recall of the Proclaim 5 Elite SCS pulse generator due to a product labeling defect. This hazard arose from changes made through the PMA supplementation process.

25. These recalls illustrate that the cumulative effect of Abbott's modifications significantly impacted device performance and patient safety. Had these changes been submitted

for a new PMA, as required by 21 C.F.R. § 814.39(a), the public, medical community, and FDA advisory panels would have had the opportunity to evaluate the altered risk-benefit profile before widespread market use.

26. Instead, Abbott was permitted to bypass that obligation. As a result, Plaintiff received multiple devices that were fundamentally different from the system described in the original PMA, with undisclosed risks and unvalidated functionality that ultimately failed and caused her significant injury and lasting harm.

27. That decision, coupled with the FDA's tolerance of over 200 design-altering PMA supplements over the next 20 years, allowed Abbott to retain the litigation shield of PMA preemption while evading the corresponding regulatory burdens. This conduct exemplifies a dual-track deception: one track for approval, another for modification and marketing. This pattern of agency leniency is precisely the type of unchecked administrative discretion that the Supreme Court curtailed in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

28. Boston Scientific's spinal cord stimulator product line originates from PMA P030017, initially approved by the FDA in 2004 for its Precision Spinal Cord Stimulator System.

29. Since the original approval of P030017, Boston Scientific has introduced numerous subsequent models and upgrades under PMA supplements, including the Precision Plus, Precision Spectra, and Spectra WaveWriter systems.

30. These newer generations of devices incorporated significant modifications, including multiwaveform stimulation (simultaneous tonic, burst, and sub-perception modes), posture-adaptive programming, expanded electrode arrays, Bluetooth-enabled programming, and major revisions to battery architecture and lead designs.

31. Boston Scientific marketed its Spectra WaveWriter system and successor models while omitting material risk information known to the manufacturer that would have been important to physicians and patients when deciding whether implantation was appropriate.

32. The defects alleged herein concern the PMA-approved spinal cord stimulation system and its component parts implanted in Plaintiffs.

33. Over time, Boston Scientific introduced substantial modifications to the originally approved Precision SCS system, including:

- The addition of simultaneous multiwaveform stimulation, including tonic, burst, and sub-perception programming (PMA Supplement P030017/S015, approved November 14, 2012);
- The redesign of the implantable pulse generator battery system and addition of Bluetooth-enabled wireless communication capabilities (PMA Supplement P030017/S032, approved August 9, 2016);
- The integration of posture-adaptive stimulation algorithms (PMA Supplement P030017/S032);
- The expansion of lead configurations and multi-source current delivery systems (PMA Supplements P030017/S015 and S032).

34. These modifications affected the device's performance characteristics and created risk information material to physician treatment decision-making that a reasonably prudent manufacturer would communicate to healthcare providers and patients.

35. After implementing design and performance changes, a reasonably prudent manufacturer would evaluate resulting safety information and communicate material risk information necessary for physicians to make informed treatment decisions.

36. Boston Scientific possessed safety information concerning performance limitations and complications associated with the device but did not adequately communicate that information to physicians and patients.

37. The omission of this information deprived treating physicians of material risk information necessary to evaluate whether implantation was appropriate.

38. Publicly available MAUDE (Manufacturer and User Facility Device Experience) database entries, peer-reviewed studies, and post-market surveillance data demonstrate that Boston Scientific's SCS systems are associated with serious complications, including:

- Device migration and loss of therapeutic coverage;

- Lead fractures requiring surgical revision;
- Battery depletion and communication failures;
- Stimulation-induced autonomic dysfunction, including urinary incontinence and orthostatic hypotension;
- Persistent ineffective pain relief despite extensive reprogramming.

39. Despite knowledge of these adverse outcomes, Boston Scientific did not communicate updated risk information to physicians and patients that a reasonably prudent medical device manufacturer would disclose for informed medical decision-making.

40. Peer-reviewed literature has increasingly associated SCS therapy, particularly multiwaveform stimulation platforms like Spectra WaveWriter, with autonomic side effects that required communication of risk information to physicians and patients.

V. REGULATORY FRAMEWORK AND FEDERAL DUTIES

41. The FDA regulates Class III medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. Class III devices, including spinal cord stimulators, pose the highest risk to patient safety and are subject to the most stringent regulatory controls, including premarket approval ("PMA") and post-market surveillance.

42. Manufacturers of PMA devices may not make changes that affect safety or effectiveness without prior approval of a new PMA or a panel-track supplement. See 21 C.F.R. § 814.39(a). This regulation imposes a nondiscretionary duty: material changes, whether in firmware, battery chemistry, stimulation parameters, user interfaces, or surgical instrumentation, require full review and public validation.

43. PMA approval also imposes ongoing federal duties, including:

- Postmarket adverse event reporting under 21 C.F.R. Part 803;
- Compliance with design controls (21 C.F.R. § 820.30);
- Manufacturing process validation (21 C.F.R. § 820.75);
- Complaint investigations and corrections under the CAPA rule (21 C.F.R. § 820.100);

- Truthful and non-misleading labeling, updated through 21 C.F.R. § 814.39(d).

44. The spinal cord stimulator implanted in Plaintiff's body was not approved based on independent clinical trial data, but rather on a finding by the FDA that the device was "sufficiently similar" to other SCS systems reported in the literature. See Summary of Safety and Effectiveness Data, P010032B, § 1.11. This "sufficient similarity" standard is less rigorous than the "substantial equivalence" requirement for 510(k) Class II clearance. Yet, it served as the evidentiary basis for granting Abbott's devices the powerful preemption protections afforded by PMA status.

45. In 2001, Advanced Neuromodulation Systems (ANS), the original sponsor of this device, submitted a petition asking the FDA to reclassify its SCS system from Class III to Class II. An expert advisory panel reviewed the data and agreed that reclassification was appropriate. The FDA overruled its own panel and denied the petition. Thereafter, the FDA approved the device as a Class III product, based not on new human clinical evidence, but on its alleged similarity to prior-generation devices.

46. That decision, coupled with the FDA's tolerance of nearly 250 design-altering PMA supplements over the next 20 years, allowed Abbott to retain the litigation shield of PMA preemption while evading the corresponding regulatory burdens. This conduct exemplifies a dual-track deception: one track for approval, another for modification and marketing.

47. If spinal cord stimulator manufacturers wish to benefit from PMA preemption, they must also bear the burden of compliance. Courts should not allow them to weaponize preemption as both sword and shield while quietly discarding the regulatory obligations that rationalize and support that protection.

48. The FDA has a statutory duty to prevent this erosion of Class III protections. By permitting Abbott to transform its device architecture without public clinical review, the agency has undermined the integrity of the PMA process.

VI. PLAINTIFF-SPECIFIC FACTUAL ALLEGATIONS

49. Plaintiff suffers from Multiple Sclerosis, and is required to undergo regular Magnetic Resonance Imaging (MRI) procedures to treat and track her illness.

50. Plaintiff was surgically implanted with a Boston Scientific SCS in 2013.

51. Plaintiff underwent surgery to replace her Boston Scientific SCS after discovering that the device's leads were migrating.

52. On or about January 22, 2021, Plaintiff underwent surgery to remove her Boston Scientific SCS due to continued lead migration.

53. On or about August 19, 2021, Plaintiff was surgically implanted with an Abbott permanent SCS.

54. Plaintiff was told that the SCS devices would relieve most of Plaintiff's pain. In reality, the device provided limited pain relief, caused shocking and burning sensations, lead migration, and lead breakage, despite being both initially programmed by the sales representative as well as being reprogrammed after the initial programming.

55. Immediately after the permanent implant surgery, representatives programmed and made therapeutic adjustments to the SCS system without meaningful physician supervision. This continued to occur on multiple occasions after Plaintiff was implanted with the SCS system.

56. Plaintiff underwent a final surgical intervention to remove the Abbott SCS system due to mechanical and therapeutic failure of the device.

57. Following the removal of Plaintiff's Abbott SCS system, it was discovered that the device's leads had fractured and embedded in her spine and pelvis. As a result, Plaintiff is no longer able to undergo medically necessary MRI procedures.

58. Throughout the time that Plaintiff was implanted with a SCS system manufactured by Abbott, Boston Scientific, or their predecessors, she was required to undergo additional procedures.

59. All leads used in the SCS systems implanted in Plaintiff were manufactured and sold by Abbott, Boston Scientific or their predecessors, depending on the device implanted at the time.

60. As a direct and proximate result of the defective and misrepresented nature of the devices, Plaintiff suffered physical injury, worsening pain, emotional distress, and economic damages including medical expenses and loss of quality of life.

61. Plaintiff discovered the probable causal relationship between their injuries and Defendants' conduct only after experiencing multiple continued device-related complications, final removal of the device, and being informed about the underlying facts of the SCS that contradicted Defendants' representations.

62. Until Plaintiff learned the underlying facts of the safety and efficacy of Abbott and Boston Scientific's SCS devices, she continued to believe that her conditions and the efficacy of the devices were an aberration limited herself and not caused by a pattern and practice of the devices manufactured by Boston Scientific and Abbott.

63. During all times relevant to this Complaint Abbott and Boston Scientific fraudulently concealed from Plaintiff the truth regarding the safety and efficacy of the SCS devices, and Plaintiff could not have, with reasonable due diligence, have determined such truth. In fact, to this day, Abbott and Boston Scientific continue to insist that their SCS devices are safe and efficacious.

VII. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

64. At all times relevant to this Complaint, Abbott Laboratories, Boston Scientific, or their predecessors were responsible for the design, manufacture, testing, labeling, promotion, sale, post-market surveillance, and regulatory compliance of the spinal cord stimulator (SCS) system implanted in Plaintiff.

65. The devices marketed to Plaintiff and her healthcare providers bore little resemblance to the device originally approved under their original PMAs. These devices incorporated multiple significant changes to their hardware, firmware, user interface, waveform architecture, battery system, and wireless programming, each of which materially impacted the devices' safety, performance, and failure modes.

66. Despite these changes, Abbott and Boston Scientific never submitted new PMAs. Instead, the companies each submitted over 200 piecemeal supplements—many of which were processed under expedited review programs, including 30-day notices and real-time reviews—avoiding panel-track scrutiny and clinical revalidation.

67. Abbott and Boston Scientific failed to disclose that the devices implanted in Plaintiff's body had never been tested through a full PMA-level clinical trial in human patients. The original approval of their respective PMAs were based not on manufacturer-sponsored trials, but on FDA conclusions that those SCS systems were "sufficiently similar" to other devices discussed in the literature. This flawed evidentiary standard was accepted by the FDA only after it overruled its own expert advisory panel, which had recommended reclassifying SCS devices from Class III to Class II.

68. Abbott and Boston Scientific relied on the full preemption shield of PMA status to market its device as safe and effective, while knowingly and repeatedly altering the system beyond what was originally validated. They failed to notify physicians or patients that the implanted device:

- Used firmware-dependent control systems absent from the predicate;
- Allowed smartphone-based patient programming via Bluetooth;
- Delivered burst and high-frequency stimulation patterns not subject to human testing under the PMA;
- Was affected by lead migration, lead breakage, communication delays, and unpredictable charging performance, as documented in MAUDE reports and adverse event summaries.

69. Between 2020 and 2023, Abbott initiated multiple recalls involving the Proclaim system. On September 11, 2023, the FDA classified five recalls of Abbott's Proclaim XR and Proclaim DRG IPGs as Class I—its most serious category, reserved for devices that may cause serious injury or death.

70. These recalls were issued in response to patient complaints of:

- Painful electrical shocks;
- Sudden unintended stimulation;
- Loss of therapy;
- Device failure during recharging;
- Malfunctioning wireless communication and programming failures.

71. These malfunctions were directly linked to design and firmware changes made in PMA supplements between 2017 and 2022, including supplements S036 (Bluetooth programming), S043 (Proclaim XR rebranding), and subsequent firmware updates approved in S051–S062. Abbott knew or should have known that these cumulative changes significantly altered the device's safety and effectiveness.

72. On May 16, 2024, Abbott initiated a recall of the Proclaim 5 Elite SCS pulse generator due to a product labeling defect, arising from product labeling changes it had made to the device in Supplement S151. The product labeling of the Proclaim Elite SCS system was never subjected to PMA review and scrutiny.

73. Abbott failed to update product labeling, device manuals, or promotional materials to reflect the true performance characteristics of the altered device. Nor did it warn physicians or patients of the risks of stimulation failure, lead migration, charging errors, nerve damage, and device failure—despite mounting adverse event reports and internal design change documentation.

74. Abbott also failed to maintain adequate design validation and risk analysis documentation as required under 21 C.F.R. § 820.30(g), and failed to investigate and address post-market complaints as required by 21 C.F.R. § 820.198 and § 820.100.

75. These violations of FDA-mandated Current Good Manufacturing Practices (cGMPs) were not isolated or inadvertent. They reflect a systemic disregard for regulatory obligations, a practice of iterative design without public revalidation, and a prioritization of market expansion over patient safety.

76. The defects in the Eon, Protégé MRI, and Proclaim systems, their design, firmware, labeling, and risk disclosure, were a direct and proximate cause of Plaintiff's injuries. These defects existed at the time the device left Abbott's control and were not known or reasonably knowable to Plaintiff or her physicians at the time of implantation.

77. At all relevant times, Plaintiff used the product as intended and in a foreseeable manner. The product failed to perform as represented, and the manifested risks were not disclosed in the device's labeling, Instructions for Use, or patient education materials.

78. Abbott's conduct was knowing, deliberate, and reckless. It knowingly placed a materially altered medical device into the stream of commerce, misrepresented its safety and approval status, and failed to correct known defects through regulatory pathways available under federal law.

79. Upon information and belief, the Proclaim Elite SCS system and related system components implanted in Plaintiff deviated from Abbott's FDA-approved manufacturing specifications for firmware execution stability, wireless programming reliability, and charging cycle consistency. These deviations resulted in stimulation shutoff, painful electric shocks, and therapy loss, all of which Plaintiff experienced and have been reported by other users of the same device model.

80. The malfunctions leading to recalls of the Proclaim system reflect systemic deficiencies in Abbott's manufacturing processes and a failure to conform to its Quality System Regulation (QSR) obligations under 21 C.F.R. §§ 820.30(g), 820.75, 820.198, and 820.100. Abbott failed to adequately validate or monitor these performance characteristics post-market, despite prior complaints and adverse event reports.

81. The devices implanted in Plaintiff were not reasonably safe at the time they left Abbott, Boston Scientific, and their predecessors' control, and their malfunction during regular use, which included loss of therapy and the need for surgical revision and removal, were a direct and foreseeable consequence of Abbott and Boston Scientific's failure to ensure adherence to its approved manufacturing controls. Plaintiff's injuries were not caused by a known or disclosed

risk; rather, they stemmed from a defect in the execution of the product's firmware and power management systems, which were neither tested nor monitored in accordance with binding federal regulations. Moreover, these injuries resulted from latent manufacturing deviations, particularly in firmware execution and power management, that were not reflected in labeling or Instructions for Use and were undetectable by implanting physicians.

CAUSES OF ACTION

I. Count I: Strict Products Liability – Manufacturing Defect

82. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

83. At all times relevant to this action, Abbott and Boston Scientific were engaged in the business of designing, manufacturing, testing, labeling, distributing, and selling medical devices, including the spinal cord stimulator systems implanted in Plaintiff.

84. The devices implanted in Plaintiff were not reasonably safe for their intended use due to a manufacturing defect. The products, as manufactured and sold, deviated from Abbott and Boston Scientific's own FDA-approved specifications and did not conform to the design and performance standards described in PMA P010032 and its associated supplements.

85. Specifically, as detailed in preceding allegations, the Proclaim XR system implanted in Plaintiff failed to conform with federal Quality System Regulations, including 21 C.F.R. §§ 820.30(g) (design validation), 820.75 (process validation), 820.100 (corrective and preventive action), and 820.198 (complaint handling). These violations resulted in systemic defects in firmware execution, wireless programming reliability, and battery charging performance.

86. These deviations were not theoretical. Plaintiff's implanted device failed during normal and foreseeable use, producing painful sensations, stimulation loss, and other adverse effects that led to surgical removal and permanent injury.

87. Plaintiff's injuries were not caused by a known or inherent risk of the device when properly manufactured, but rather by a departure from its intended and approved construction.

The product failed to perform as represented, and it would not have failed but for Abbott and Boston Scientific's failure to comply with FDA-mandated specifications and manufacturing protocols.

88. Under California, Florida, Indiana and Illinois law, Abbott and Boston Scientific are strictly liable for injuries caused by a manufacturing defect that rendered the device unreasonably dangerous at the time it left its control.

89. As a direct and proximate result of the manufacturing defect in the device, the Plaintiff suffered physical injury, pain, medical expenses, loss of enjoyment of life, and other damages.

II. Count II: Strict Products Liability – Failure To Warn

90. Plaintiff incorporates by reference allegations set forth above as though fully set forth herein.

91. At all times relevant, Abbott and Boston Scientific had a duty to provide adequate warnings and instructions regarding the known or reasonably foreseeable risks associated with their spinal cord stimulator systems.

92. Under California, Florida, Indiana and Illinois law, a product is defective if it is unreasonably dangerous due to the absence of adequate warnings or instructions. This duty extends to risks known or knowable in light of the scientific, clinical, or regulatory knowledge available at the time the product was marketed and distributed.

93. The spinal cord stimulator devices implanted in Plaintiff were materially altered from the system originally approved under their respective PMAs. The systems she received included functionality that was never clinically validated in human trials or publicly disclosed at the time of approval.

94. Abbott and Boston Scientific failed to update their Instructions for Use (IFU), patient education materials, and physician-facing labeling to disclose: the risk of painful stimulation spikes or loss of therapy during wireless charging; the instability of firmware updates and potential for loss of device communication; the increased rate of lead migration and therapy

failure reported post-market; the cumulative nature of the device's evolution, and that its current form bore little resemblance to the device described in their original PMAs or their Summary of Safety and Effectiveness Data.

95. The failure to warn was compounded by Abbott and Boston Scientific's internal knowledge of these risks, including MAUDE reports, post-market complaint data, and prior design and validation issues. Despite this knowledge, Abbott and Boston Scientific continued to represent the device as "safe and effective" and failed to initiate field safety notifications, device labeling changes, or provider education consistent with 21 C.F.R. § 814.39(d) or 21 C.F.R. § 820.198.

96. Plaintiff and her healthcare providers reasonably relied on Abbott and Boston Scientific's representations and omissions in deciding to proceed with implantation of the SCS devices. Had they been adequately warned of the known risks, the device would not have been implanted, or alternative treatments would have been pursued.

97. Plaintiff's injuries were caused in whole or in part by Abbott and Boston Scientific's failure to warn of known or knowable dangers associated with the use of their products. These failures rendered the device unreasonably dangerous for its intended use and constitute a defect under California, Florida, Indiana and Illinois law.

98. As a direct and proximate result of Abbott and Boston Scientific's failure to warn, Plaintiff suffered physical injury, pain, medical costs, surgical intervention, emotional distress, and other damages.

III. Count III: Negligence Per Se – Federal Regulatory Violations

99. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

100. Under California, Florida, Indiana, and Illinois law, a person injured by the violation of a statute or regulation intended to protect the class of persons to which that person belongs may recover damages under a theory of **negligence per se**.

101. Abbott and Boston Scientific were subject to, and violated, multiple non-discretionary federal duties that were enacted for the protection of public health and safety. These duties are embodied in the Food, Drug, and Cosmetic Act (FDCA), the Medical Device Amendments of 1976, and FDA regulations promulgated thereunder, including:

21 C.F.R. § 814.39(a) – requiring new PMAs for changes that may affect device safety or effectiveness;

21 C.F.R. § 803.50 – mandating adverse event reporting;

21 C.F.R. § 820.30(g) – requiring design validation under expected use conditions;

21 C.F.R. § 820.75 – requiring process validation to ensure consistent device output;

21 C.F.R. § 820.198 – requiring investigation of complaints;

21 C.F.R. § 820.100 – mandating corrective and preventive action (CAPA) when product failures are identified;

21 C.F.R. § 814.39(d) – requiring labeling updates in response to known risks.

102. The devices implanted in Plaintiff materially deviated from the system approved in their original PMAs. They incorporated design and firmware changes that altered their safety profile, yet Abbott and Boston Scientific failed to file a new PMA or submit panel-track supplements, as required by 21 C.F.R. § 814.39(a). Abbott and Boston Scientific instead submitted piecemeal supplements and exploited expedited review programs to bypass clinical safety validation.

103. Abbott and Boston Scientific also failed to report adverse events linked to stimulation shutoff, therapy loss, and electrical shocks under 21 C.F.R. § 803.50. These adverse effects were known to Abbott and Boston Scientific prior to Plaintiff's implantation and were consistent with reports subsequently leading to Class I recalls in 2023.

104. Abbott and Boston Scientific violated design and manufacturing regulations by failing to validate the performance of systems. They also failed to initiate CAPA processes in response to known problems, and did not investigate or disclose known product complaints in accordance with 21 C.F.R. §§ 820.100 and 820.198.

105. Each of these violations constitutes a breach of federal laws that were designed to protect a class of persons, of which Plaintiff is a member, against a particular type of harm.

106. Plaintiff is a member of the class of persons these statutes and regulations are intended to protect: patients receiving high-risk Class III medical implants under the FDA's PMA regulatory framework. Plaintiff's injuries are of the type these laws are intended to prevent—namely, harm resulting from undisclosed and unremedied device malfunctions that occur due to failures in quality systems, post-market reporting, and product validation.

107. As a direct and proximate result of Abbott and Boston Scientific's violations of federal regulations and California, Illinois, Indiana, and Florida law, Plaintiff suffered compensable physical injury, pain, medical costs, loss of enjoyment of life, and other damages.

108. These regulatory violations were not merely technical infractions, but material breaches of duties specifically intended to prevent the type of harm suffered by Plaintiff—namely, therapy loss, neurological injury, and delayed surgical intervention due to systemic firmware and charging failures.

IV. Count IV: Breach Of Express Warranty

109. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

110. Under California, Florida, Indiana, and Illinois law, an express warranty is created when a seller makes an affirmation of fact or promise to the buyer that relates to the goods and becomes part of the basis of the bargain.

111. Prior to the implantation of the spinal cord stimulator devices, Abbott and Boston Scientificmade explicit representations in their promotional materials, device labeling, Instructions for Use (IFU), public statements, and directly to Plaintiff that the devices were safe, effective, reliable, and had been adequately tested for use in human patients suffering from chronic pain.

112. Abbott and Boston Scientific expressly warranted that their SCS devices provided consistent pain relief, seamless therapy delivery, safe wireless programming, and a rechargeable

platform with superior reliability and patient comfort. Abbott and Boston Scientific's provider materials represented that its SCS systems were "FDA-approved," "clinically validated," and "designed for long-term use with low complication rates." These claims were repeated in sales brochures, website copy, and Abbott and Boston Scientific's physician training materials.

113. These affirmations and promises became part of the basis of the bargain between Abbott, Boston Scientific, and Plaintiff, as well as Plaintiff's implanting physicians. Plaintiff and her physicians relied on these representations to proceed with the implantation of the SCS system.

114. In fact, the SCS systems implanted in Plaintiff had never undergone clinical validation in its final marketed form. The FDA approved the system based on "sufficient similarity" to earlier devices, not on Defendants' sponsored clinical trial data specific to the device actually implanted. Defendants failed to disclose that their devices had been significantly altered through over 200 PMA supplements, nor that these changes materially affected the device's safety and reliability.

115. The devices failed to perform as promised. Plaintiff experienced therapy loss, painful electrical sensations, lead migration and breakage, and which required surgical revision and removal. The products were not safe, effective, or reliable as expressly warranted by Abbott and Boston Scientific, and Defendants failed to provide adequate warnings or updates contradicting its original claims.

116. Defendants' breach of its express warranties directly and proximately caused Plaintiff's injuries. Had the devices performed as warranted, Plaintiff would not have suffered worsening pain, adverse symptoms, or required surgical intervention.

117. As a result of this breach of express warranty, Plaintiff is entitled to recover all compensatory damages allowed under the law, including medical expenses, pain and suffering, and other economic and noneconomic losses.

V. Count V: Breach Of Implied Warranty Of Merchantability And Fitness For A Particular Purpose

118. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

119. Under California, Florida, Indiana, and Illinois law, a seller who is a merchant with respect to goods of that kind warrants that the goods shall be merchantable and fit for the ordinary purposes for which such goods are used.

120. Abbott and Boston Scientific are merchants engaged in the business of manufacturing, marketing, and selling spinal cord stimulator systems, including systems implanted in Plaintiff. These devices are used for the ordinary purpose of treating chronic pain through safe and effective neuromodulation therapy.

121. When Abbott and Boston Scientific marketed and sold their SCS systems implanted in Plaintiff, they impliedly warranted that the devices were of merchantable quality, conformed to FDA-approved specifications, and were reasonably safe for its intended medical purpose. Abbott and Boston Scientificalso impliedly warranted that the devices were fit for the specific purpose of long-term implantation to treat Plaintiff's condition, as recommended by her physicians.

122. The devices implanted in Plaintiff were not of merchantable quality, nor were they fit for their intended purpose. They failed to operate as expected due to known defects in firmware execution, wireless programming, battery recharging, lead migration, lead breakage, and therapy delivery. Plaintiff experienced painful shocks, burning, therapy failure, and ultimately underwent surgical removal due to the multiple product's unreliability and malfunction.

123. These failures were not caused by misuse or physician error. They were the direct result of design-altering changes Abbott and Boston Scientific implemented without corresponding clinical testing or validation, and without disclosing these risks in labeling or provider materials. The devices failed to conform to the minimum standards of merchantability and fitness for long-term neuromodulation therapy.

124. Abbott and Boston Scientific's breach of implied warranties was a proximate cause of Plaintiff's injuries, including physical pain, surgical intervention, economic loss, and

emotional distress. Plaintiff would not have consented to the implantation had she or her physician known the device was unfit for its intended use.

VI. Count VI: Negligence

125. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

126. Abbott and Boston Scientificowed Plaintiff a duty of reasonable care in the design, development, manufacture, labeling, testing, marketing, sale, and post-market surveillance of the spinal cord stimulator systems that they placed into the stream of commerce.

127. Abbott and Boston Scientific breached their duty of care in one or more of the following ways:

a. By negligently failing to ensure that the devices were manufactured in accordance with FDA-approved specifications, including labeling, firmware, battery safety, and programming reliability standards;

b. By negligently introducing cumulative design changes through successive PMA supplements without proper validation, public clinical testing, or physician disclosure;

c. By negligently failing to investigate known risks associated with stimulation loss, painful shocks, and therapy failure, despite premarket complaints, post-market adverse event reports, and internal device testing;

d. By negligently failing to update their Instructions for Use, provider communications, or promotional materials in accordance with 21 C.F.R. § 814.39(d) and 21 C.F.R. § 820.198, despite known malfunctions;

e. By negligently failing to report adverse events related to their SCS systems in accordance with 21 C.F.R. Part 803;

f. By failing to initiate corrective and preventive actions under 21 C.F.R. § 820.100 after receiving adverse reports of stimulation instability, lead migration, or battery failure consistent with the experience of Plaintiff and other patients.

128. These negligent acts and omissions constitute breaches of both Abbott and Boston Scientific's duties under California, Florida, Indiana and Illinois common law and its nondiscretionary regulatory obligations under the FDCA and FDA regulations, including 21 C.F.R. Part 803, 21 C.F.R. §§ 820.30(g), 820.75, 820.100, 820.198, and 814.39(a)–(d). These regulatory violations support a state-law claim for negligence and are not preempted under *Riegel v. Medtronic* or *Buckman v. Plaintiffs' Legal Committee*. Abbott and Boston Scientific's deviation from these standards was not isolated, but systemic, as evidenced by repeated internal and public reporting of identical failure modes across multiple product models.

129. California, Florida, Indiana, and Illinois law similarly imposes a duty on manufacturers to exercise ordinary care in the design, manufacture, labeling, and distribution of medical devices, including duties to investigate known hazards and warn of risks not adequately disclosed.

130. Abbott and Boston Scientific's breach of their duties of care caused Plaintiff's injuries. As alleged above, Plaintiff suffered painful device malfunction and therapy failure resulting in surgical revision and eventual removal of the SCS systems. These harms were foreseeable and preventable had Abbott and Boston Scientific exercised reasonable care.

131. As a direct and proximate result of Abbott and Boston Scientific's negligence, Plaintiff suffered physical pain, emotional distress, financial harm, and other compensable damages.

VII. Count VII: Negligent Misrepresentation

132. Plaintiff incorporates by reference all allegation set forth above as though fully set forth herein.

133. At all times relevant, Abbott and Boston Scientific, in the course of their business, made representations to healthcare providers, patients, and the general public regarding the safety, effectiveness, regulatory status, and performance of their spinal cord stimulator systems.

134. Abbott and Boston Scientific represented, through promotional materials, Instructions for Use, patient education resources, and provider training, that their SCS devices:

were safe and effective for the long-term treatment of chronic pain; were fully FDA-approved and compliant with all applicable regulations; had been validated through rigorous clinical trials or otherwise demonstrated safe through FDA-approved testing; and maintained reliability in therapy delivery, stimulation programming, and battery recharging.

135. These representations were false. As set forth in the preceding allegations, Abbott and Boston Scientific failed to disclose that: the Abbott or Boston Scientific devices had never been clinically validated in their marketed form; these devices had undergone significant design and firmware changes through more than 200 PMA supplements; These changes materially altered their performance and introduced new, untested risks; and multiple recalls and adverse events had already emerged related to therapy shutoff, stimulation spikes, battery failure, and wireless programming.

136. Abbott and Boston Scientific made these misrepresentations and omissions in a commercial context, intending physicians and patients to rely on them in making decisions regarding device selection, implantation, and long-term management.

137. Abbott and Boston Scientific also made these misrepresentations directly to Plaintiff through their physicians and through their sales representatives, who misrepresented to Plaintiff that the permanent SCS systems would provide Plaintiff with long term pain relief, were safe and backed by clinical validation, would be functionally equivalent to the trial SCS system, and would alleviate Plaintiff's need to receive other treatment for her chronic pain.

138. Plaintiff's treating physicians reasonably relied on Abbott and Boston Scientific's misrepresentations when selecting the Abbott and Boston Scientific system for implantation. Plaintiff, in turn, relied on the statements made by Abbott and Boston Scientific, including assurance of FDA approval, therapy safety, and reliability, when consenting to implantation.

139. Abbott and Boston Scientific failed to exercise reasonable care in obtaining or communicating accurate information about the device's clinical validation, safety risks, and actual approval history. A reasonable manufacturer in Abbott or Boston Scientific's position

would have known, or should have known, that its cumulative modifications had introduced serious safety issues and altered the nature of the devices from its predicate.

140. As a direct and proximate result of Abbott and Boston Scientific's negligent misrepresentations and omissions, Plaintiff suffered foreseeable physical and economic harm, including the pain and cost of unnecessary and dangerous implantation and eventual revision surgery.

141. For avoidance of doubt, Plaintiff alleges misrepresentations were made to her and her healthcare providers, not the FDA.

VIII. Count VIII: Fraudulent Concealment

142. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

143. At all times relevant, Abbott and Boston Scientifichad superior knowledge of critical facts concerning the safety, efficacy, and approval history of their spinal cord stimulator systems—information not available to Plaintiff, her treating physicians, or the general public.

144. Abbott and Boston Scientific were under a duty to disclose material facts relating to the performance and risks of the SCS systems due to: exclusive access to adverse event reports and internal product complaint data; control over PMA supplement disclosures and labeling updates; direct and indirect representations to patients and physicians; statutory and regulatory duties under 21 C.F.R. §§ 803.50, 814.39, and 820.198 to disclose newly acquired safety information.

145. Abbott and Boston Scientific actively concealed or failed to disclose that: the SCS systems had undergone extensive, untested design and firmware changes; the FDA had approved the devices based only on similarity to legacy SCS systems—not on new clinical trial data; known issues with therapy interruption, device shutdown during charging, and unintended stimulation had been internally reported, but not publicly disclosed; and that these issues resulted in multiple FDA recalls, including Class I recalls in 2023 and Class II recalls in 2024, matching the adverse experiences of Plaintiff and other patients.

146. Abbott and Boston Scientific's concealment of these material facts was intentional, or made with reckless disregard for the truth, and was undertaken to encourage widespread implantation and minimize safety concerns in order to preserve market share.

147. Plaintiff and her physicians justifiably relied on Abbott and Boston Scientific's omission of material safety information when consenting to implantation of the SCS systems. Plaintiff was unaware—and had no way of knowing—that Abbott and Boston Scientific was concealing data and risks that materially affected the safety of these devices.

148. Abbott and Boston Scientific's fraudulent concealment directly and proximately caused the Plaintiff's injuries, including her exposure to harmful device malfunctions, surgical intervention, and resulting physical and emotional harm. Had the concealed risks been disclosed, Plaintiff would not have consented to implantation. The concealment of safety-related defects amounted to active fraud in the context of patient trust and medical device implantation. For the avoidance of doubt, Plaintiff is not alleging fraud on the FDA.

IX. Count IX: Violation Of Consumer Protection Laws

149. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

150. Abbott and Boston Scientific, through their consumer-oriented marketing, labeling, promotional efforts, and public communications, engaged in false, misleading, and deceptive acts and practices in connection with the promotion and sale of their spinal cord stimulator systems that were implanted in Plaintiff.

151. These acts include: falsely advertising the devices as safe, effective, and FDA-approved without disclosing that the approved form of the device was materially altered through over 230 PMA supplements; failing to disclose known malfunctions, including painful shocks, device shutdowns, and therapy loss; omitting material information regarding recalls, firmware instability, and clinical trial limitations; and misrepresenting the scope and meaning of FDA approval to patients and providers.

152. Plaintiff was a foreseeable consumer of the device. Although she relied in part on her physician's advice, Abbott and Boston Scientific engaged in direct-to-consumer advertising and disseminated patient-facing marketing materials that contained false or misleading information.

153. Plaintiff and her physician reasonably relied on Abbott and Boston Scientific's omissions and misrepresentations when consenting to device implantation. Had the material facts been disclosed, Plaintiff would not have proceeded with implantations.

154. As a result of Abbott and Boston Scientific's statutory violations, Plaintiff suffered personal injury and economic loss and is entitled to recover all damages, equitable relief, and attorneys' fees available under state consumer protection laws.

X. Count X: Negligence Per Se – Unauthorized Practice of Medicine

155. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

156. California, Florida, Indiana, North Carolina, and Illinois law prohibits the unauthorized practice of medicine by any individual or corporate entity not licensed in their respective states. These prohibitions reflect a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

157. Abbott and Boston Scientific are not licensed to practice medicine in California, Florida, Illinois, North Carolina, Indiana or any other state. Nevertheless, Abbott and Boston Scientific exercised functional control over the administration of Plaintiff's neuromodulation therapy by: actively participating in the implantation of their SCS systems in Plaintiff's body, intra operatively programing those SCS systems, and programming the SCS system post-operatively; pushing firmware updates and stimulation programming changes remotely after implantation; designing and controlling preset therapy "profiles" that physicians could not override without manufacturer approval; and altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight.

158. These actions constitute the unauthorized practice of medicine, as they involved making decisions about the nature, extent, and delivery of Plaintiff's therapy during and after implantation, without informed consent or involvement by a licensed provider.

159. Under the law of the respective states, violation of a safety statute gives rise to negligence per se where the injured party is within the class the statute was intended to protect and the injury is of the type the statute was designed to prevent.

160. Plaintiff, as a patient undergoing neuromodulation therapy, is squarely within the protected class. Her injuries, caused by improper therapeutic manipulation without medical oversight, are the exact type the law is intended to prevent.

161. In the alternative, these laws also prohibit the unlicensed practice of medicine. Abbott's corporate conduct originating from its Illinois headquarters and Boston Scientific's corporate conduct originating from its California location, violated the law by enabling automated therapy changes and device behavior modulation outside the physician-patient relationship.

162. As a direct and proximate result of Abbott and Boston Scientific's unauthorized and unlicensed manipulation of Plaintiff's therapy, Plaintiff suffered harm, including painful stimulation, surgical revision, and other physical and emotional injuries. This harm was exacerbated by Plaintiff's loss of therapeutic control, wherein Abbott and Boston Scientific, through remote firmware updates, preset programming, and device-level automation, functionally practiced medicine by dictating post-implant treatment decisions that should have remained within the licensed provider-patient relationship.

PRAYER FOR RELIEF

163. **WHEREFORE**, Plaintiff respectfully requests that this Court enter judgment in her favor and against Defendants and award the following relief:

a. Compensatory damages in an amount to be determined at trial for physical injury, pain and suffering, emotional distress, medical expenses, loss of enjoyment of life, and all other actual damages recoverable under applicable law;

b. Statutory damages and attorney's fees and costs pursuant to any applicable consumer protection statutes;

c. Punitive or exemplary damages, as allowed by law, based on Defendant Abbott and Boston Scientific's willful, malicious, and/or reckless disregard for the safety and rights of Plaintiff and the public;

d. Attorneys' fees and costs as appropriate under the various laws;

e. Pre-judgment and post-judgment interest as provided by law;

f. The costs of this action; and

g. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMAND

164. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: April 22, 2026

Respectfully submitted,

FARR LAW FIRM P.A.

/s/ George T. Williamson
George T. Williamson
FL Bar No. 85585
99 Nesbit Street
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Attorneys for Plaintiff

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

BARBARA JARRETT

(b) County of Residence of First Listed Plaintiff Bay County, FL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

George T. Williamson, Esq., Farr Law Firm, P.A.
99 Nesbit Street, Punta Gorda, FL 33950

DEFENDANTS

ABBOTT LABORATORIES; BOSTON SCIENTIFIC CORP.; BOSTON SCIENTIFIC NEUROMODULATION CORP.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:
Products liability action for personal injuries caused by allegedly defective spinal cord stimulator

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
04/22/2026

SIGNATURE OF ATTORNEY OF RECORD
/s/ George T. Williamson

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

BARBARA JARRETT

Plaintiff(s)

v.

ABBOTT LABORATORIES;
BOSTON SCIENTIFIC CORPORATION; and
BOSTON SCIENTIFIC NEUROMODULATION CORPORATION

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ABBOTT LABORATORIES
c/o Registered Agent
100 Abbott Park Road
Abbott Park, Lake County, IL 60064

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

George T. Williamson, Esq.
FARR LAW FIRM, P.A.
99 Nesbit Street Punta
Gorda, FL 33950
Telephone: (941) 639-1158
Facsimile: (941) 639-0028
Email: gwilliamson@farr.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ _____ 0

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

BARBARA JARRETT

Plaintiff(s)

v.

ABBOTT LABORATORIES;
BOSTON SCIENTIFIC CORPORATION; and
BOSTON SCIENTIFIC NEUROMODULATION CORPORATION

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BOSTON SCIENTIFIC CORPORATION
c/o Registered Agent
300 Boston Scientific Way
Marlborough, MA 01752

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

George T. Williamson, Esq.
Florida Bar No. 85585
FARR LAW FIRM, P.A.
99 Nesbit Street
Punta Gorda, FL 33950
Telephone: (941) 639-1158
Facsimile: (941) 639-0028
Email: gwilliamson@farr.com

Attorneys for Plaintiff

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

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❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

BARBARA JARRETT

Plaintiff(s)

v.

ABBOTT LABORATORIES;
BOSTON SCIENTIFIC CORPORATION; and
BOSTON SCIENTIFIC NEUROMODULATION CORPORATION

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* BOSTON SCIENTIFIC NEUROMODULATION CORPORATION
c/o Registered Agent
2710 Gateway Oaks Drive
Sacramento, CA 95833

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

George T. Williamson, Esq.
Florida Bar No. 85585
FARR LAW FIRM, P.A.
99 Nesbit Street
Punta Gorda, FL 33950
Telephone: (941) 639-1158
Facsimile: (941) 639-0028
Email: gwilliamson@farr.com

Attorneys for Plaintiff

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

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Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: