UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

DILLY ANDERSON,

Plaintiff,

v.

MEDTRONIC, INC.;

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants.

COMPLAINT FOR DAMAGES AND DECLARATORY AND INJUNCTIVE RELIEF

I. PARTIES, VENUE, AND JURISDICTION

1. Plaintiff Dilly Anderson, also known as Dilman Anderson, is a natural person and resident of Cadiz, Kentucky, where he resided at all relevant times. He is a citizen of the Commonwealth of Kentucky for purposes of 28 U.S.C. § 1332.

2. Defendant Medtronic, Inc. is a for-profit corporation organized under the laws of the State of Minnesota with its principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604. Medtronic is a global medical device manufacturer that designs, develops, manufactures, markets, and distributes spinal cord stimulator systems throughout the United States, including the State of Kentucky.

3. Defendant United States Food and Drug Administration (FDA) is a federal agency headquartered at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993, operating under the United States Department of Health and Human Services. The FDA is responsible for reviewing and approving medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") and for regulating the marketing, labeling, and safety of Class III medical devices, including Medtronic's spinal cord stimulators. The FDA is named as a party pursuant to 5 U.S.C. §§ 702–706 and 28 U.S.C. § 1331, in connection with the agency's final actions related to Pre-Market Approval ("PMA") supplements issued to Medtronic for the subject device.

4. This Court has original subject matter jurisdiction under 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds $75,000, exclusive of interest and costs, and there is complete diversity of citizenship between the parties.

5. This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 5 U.S.C. § 702, as this action includes claims against a federal agency under the Administrative Procedure Act (APA), arising from final agency action in connection with the FDA's approval and oversight of Medtronic's Class III spinal cord stimulator device.

6. This Court has supplemental jurisdiction over Plaintiff's related state-law claims pursuant to 28 U.S.C. § 1367(a) because those

claims form part of the same case or controversy as the federal claims brought under the APA.

7. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(1)–(2) because Defendant Medtronic, Inc. resides and maintains its principal place of business in this district, and because a substantial part of the events or omissions giving rise to the claims occurred in this district, including the regulatory decisions, labeling, and post-market conduct at issue.

8. Defendants are subject to the personal jurisdiction of this Court because they reside in, conduct business in, or committed tortious acts within or directed at the State of Minnesota.

II. APPLICABLE LAW AND CHOICE OF LAW

9. This action arises under both federal and state law. Plaintiff brings federal claims against the United States Food and Drug Administration ("FDA") under the APA, 5 U.S.C. §§ 701–706, and brings state-law claims against Medtronic, Inc. for personal injuries sustained as a result of its defective spinal cord stimulator device, which was designed, marketed, and regulated from within this district.

10. Plaintiff was implanted with the subject device in the Commonwealth of Kentucky, where he resided at all relevant times and where he experienced the injuries giving rise to this lawsuit. Accordingly, Plaintiff's tort claims are governed by Kentucky law.

11. However, significant aspects of the design, manufacture, regulatory strategy, and labeling of the device occurred within the State of Minnesota. Defendant Medtronic, Inc. is headquartered in Minneapolis, Minnesota, and its spinal cord stimulator business was directed from that location at all relevant times. In addition, Medtronic's Pre-Market Approval ("PMA") applications and PMA supplement submissions to the FDA were coordinated from within this district.

12. Under Minnesota's choice of law principles, courts apply a functional approach, balancing the interests of the states whose laws are in conflict and considering factors such as predictability of results, maintenance of interstate order, simplification of the judicial task, advancement of the forum's governmental interests, and application of the better rule of law. *See Jepson v. Gen. Cas. Co. of Wis.*, 513 N.W.2d 467, 470 (Minn. 1994).

13. The Minnesota borrowing statute, Minn. Stat. § 541.31 subd. 1(a), incorporates the substantive law of the state where the injury occurred if the plaintiff resided there at the time. Here, Kentucky law governs substantive tort issues because Plaintiff's injuries occurred in Kentucky, and Plaintiff was a Kentucky resident both at the time of implantation and at the time of injury.

14. Nonetheless, to the extent Minnesota law applies to corporate conduct occurring within this district—including regulatory strategy, FDA

correspondence, and labeling decisions—Plaintiff also invokes Minnesota law in the alternative for claims involving Medtronic's corporate practices and its FDA-related decision-making.

15. Plaintiff's state-law claims are further supported by federal statutes and regulations, including the FDCA and implementing regulations under 21 C.F.R. Parts 803, 814, and 820, which establish parallel duties recognized under Kentucky and Minnesota law. These claims do not seek to enforce the FDCA but invoke state tort principles that mirror federal requirements.

III. FACTUAL ALLEGATIONS REGARDING THE SCS DEVICE & REGULATORY HISTORY

16. Spinal cord stimulation (SCS) is a neuromodulation therapy used to manage chronic, intractable pain of the trunk and/or limbs. Medtronic, Inc. was the first company to obtain Pre-Market Approval (PMA) from the FDA for a fully implantable SCS system. That approval, PMA No. P840001, was granted in 1984 for the Itrel II system and has since been expanded through over 400 PMA supplements encompassing changes to the pulse generator hardware, leads, software, firmware, stimulation waveforms, battery chemistry, surgical implantation tools, and labeling.

17. The device implanted in Plaintiff Dilly Anderson on May 30, 2018, was a Medtronic Intellis™ SCS system, Model 97715. This model was

approved under PMA P840001 and supplemented through a series of streamlined FDA processes that did not require new clinical testing, including 30-day notices and real-time review pathways.

18. The Intellis system incorporates a rechargeable pulse generator with an internal lithium-ion battery, advanced stimulation waveforms, and a digital programmer with wireless capabilities. At the time of Mr. Anderson's implantation, Medtronic marketed the Intellis system as the "smallest implantable neurostimulator on the market," promoting improved battery life, rapid recharge cycles, and patient-friendly ergonomics.

19. Despite Medtronic's marketing representations, internal adverse event reports submitted via the FDA's Medical Device Reporting (MDR) system and disclosed through the Manufacturer and User Facility Device Experience (MAUDE) database reveal a significant rate of early hardware failure, lead migration, battery depletion, and patient-reported worsening of pain. MAUDE reports associated with Model 97715 include more than 2,700 unique adverse events between 2017 and 2022, with recurring patterns of high-frequency charging failure, unintentional shocks, and stimulator migration. These risks were not adequately disclosed in the labeling, training materials, or risk mitigation strategies accompanying the device.

20. Medtronic's post-approval modifications to the Intellis system, including firmware, wireless control protocols, battery management algorithms, stimulation parameters, and physical form factor, were implemented through successive PMA supplements without new clinical trials or comparative testing. These changes materially altered the safety and functionality profile of the system but were not disclosed to physicians or patients. Many of these changes were implemented through non-panel-track supplements or real-time reviews, despite introducing features that would have required a new PMA under applicable law.

21. Under 21 C.F.R. § 814.39(a), a new PMA is required when changes to a device, individually or cumulatively, affect the device's safety or effectiveness in a significant way. Despite this requirement, the FDA permitted Medtronic to implement substantial changes to the original Itrel II device over time through piecemeal supplements, transforming the original predicate into a device with entirely different architecture, behavior, and risk profile. The following PMA supplements, all approved under PMA P840001 between 1986 and 2017, upon information and belief, illustrate the extent of these material changes:

a. S003 (Mar. 4, 1986): Introduced dual-channel stimulation capability, increasing the neurophysiological complexity and potential for off-target effects.

b. S012 (July 18, 1989): Replaced the original energy source with a lithium iodine battery, altering recharge behavior and long-term power regulation.
c. S025 (Oct. 21, 1992): Updated the lead anchoring system, affecting surgical technique and lead migration risk.
d. S043 (Apr. 10, 1995): Introduced the Itrel 3 IPG with revised circuitry, firmware controls, and physical housing, marking a significant redesign.
e. S072 (Dec. 15, 2000): Enabled software-based reprogramming via external programmer, introducing code-dependent stimulation modulation.
f. S102 (May 13, 2004): Approved the Synergy system, incorporating variable stimulation waveforms and multiprogram user toggling.
g. S150 (July 29, 2008): Introduced wireless telemetry and a redesigned patient programmer, introducing new cybersecurity and signal integrity considerations.
h. S201 (Nov. 17, 2011): Added MRI compatibility through SureScan labeling, requiring shielding, device tracking, and material changes.
i. S278 (June 5, 2015): Altered firmware and battery controller software for adaptive charging behavior, without clinical testing of long-term performance.
j. S327 (June 15, 2017): Launched the Intellis Model 97715 featuring a novel form factor, rechargeable battery platform, updated charging telemetry, and an entirely new device-user interface culminating decades of unreviewed transformation and representing a fundamental redesign of the implantable pulse generator (IPG) platform.

k. S331 (Approved August 10, 2017): Modified charging algorithm firmware and wireless telemetry protocols. These changes affected energy transfer efficiency and battery lifespan, raising concerns regarding overheating and early depletion.

l. S345 (Approved March 13, 2018): Added new stimulation waveform parameters and dynamic adjustment algorithms. These functions were not present in the Itrel II and may affect neural response and long-term tissue interface.

m. S354 (Approved July 2, 2018): Modified the clinical workflow and reprogramming interface, altering physician-user interaction and device tuning processes. This supplement also adjusted stimulation thresholds and cycling rates.

n. S359 (Approved October 23, 2018): Integrated Medtronic's proprietary SureScan MRI labeling and introduced updated implant materials, further differentiating the device from earlier predicate models..

22. These cumulative changes, spanning hardware design, software control, stimulation delivery, energy source, and interface protocols, materially altered the mechanism of action, clinical handling, and risk profile of the Medtronic SCS system. The device implanted in Plaintiff bore only nominal resemblance to the Itrel II system originally reviewed by the FDA. Nevertheless, neither Medtronic nor the FDA required a new PMA, despite crossing the regulatory threshold for re-review under § 814.39(a). By 2018, Medtronic was aware through internal

complaint tracking and post-market surveillance of numerous reports of early-onset pain flare-ups, electrical shocks, and unintended stimulation related to the Model 97715 system. The MAUDE database includes consistent adverse event narratives describing "shock-like sensations," "burning pain worse than before the implant," "rapid loss of charge," and "non-functional devices within months of implantation." These complications were reported not only by patients but also by providers and field representatives. Nevertheless, the company continued to market the device as safe and effective for long-term use.

23. The FDA, in turn, approved many of these changes through expedited channels without convening advisory committees or requiring Medtronic to submit new clinical safety data. The agency's regulatory oversight failed to ensure that subsequent versions of the Intellis system, including the configuration implanted in Mr. Anderson, met the same standards for safety and effectiveness as the original approved device.

IV. REGULATORY FRAMEWORK AND FEDERAL DUTIES

24. The Medtronic spinal cord stimulator system implanted in Plaintiff was subject to the regulatory requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., and its implementing regulations. As a Class III medical device, the system was required to undergo Pre-Market Approval by the FDA prior to marketing.

25. The original PMA for Medtronic's spinal cord stimulator system, PMA No. P840001, was approved in 1984 for the Itrel II system. Since that time, Medtronic has submitted over 400 PMA supplements for successive modifications to the device's design, software, firmware, stimulation algorithms, battery, and labeling. These supplements were reviewed and approved under 21 C.F.R. § 814.39, which provides separate pathways for "panel-track" supplements requiring clinical data, and expedited or "real-time" supplements that may proceed without new trials.

26. Under 21 C.F.R. § 814.39(a), a new PMA is required if a device modification affects safety or effectiveness to a degree that the change is "significant" and not appropriately evaluated through a supplemental pathway. Such significant modifications include changes to the device's design, materials, energy source, software, indications, or mechanism of action. A manufacturer may not evade this requirement by serially supplementing a PMA with cumulative modifications that, when taken together, materially alter the device from its originally approved form.

27. FDA guidance documents, including Deciding When to Submit a 510(k) for a Software Change to an Existing Device (Oct. 25, 2017), and Real-Time Premarket Approval Supplement Review Program (Apr. 2019), confirm that changes to a device's software architecture, user interface, stimulation parameters, or risk controls require a new PMA or panel-track supplement if the cumulative effect is clinically meaningful.

28. As a device manufacturer, Medtronic was obligated to comply with the FDA's Quality System Regulation (QSR), 21 C.F.R. Part 820, which establishes Current Good Manufacturing Practices (cGMP) for medical devices. This includes mandatory controls for design validation, change management, process controls, complaint handling, adverse event reporting, device history records, and corrective and preventive actions (CAPA).

29. Medtronic was also required to submit Medical Device Reports (MDRs) to the FDA under 21 C.F.R. Part 803 upon receiving or becoming aware of information that reasonably suggested one of its devices may have caused or contributed to a death or serious injury, or that a malfunction would likely recur.

30. As part of its PMA responsibilities, Medtronic was further obligated to comply with post-approval conditions under 21 C.F.R. § 814.82(a), including maintaining records of design changes, disclosing relevant adverse event trends, and ensuring that labeling accurately reflected known device risks.

31. The FDA, in turn, was required to enforce these regulations through its oversight authority, including review of PMA supplements, audits under 21 C.F.R. § 820.1 et seq., and enforcement actions when safety signals or manufacturing deficiencies emerged. When the agency approves PMA supplements or permits devices to remain on the market despite

cumulative changes that warrant new safety review, such actions constitute final agency action subject to judicial review under the APA, 5 U.S.C. §§ 702–706.

32. The FDA's decisions to approve Medtronic's PMA supplements without requiring panel-track review, additional clinical trials, or updated risk disclosures represent final actions under the APA. These decisions materially impacted Plaintiff, who was implanted with a device materially altered from its original approved form without his knowledge or the informed consent of his surgeon.

33. In addition to its duties under the PMA framework, Medtronic was required to file Medical Device Reports (MDRs) with the FDA for each reportable adverse event under 21 C.F.R. § 803.50. Medtronic further had a continuing obligation to revise its product labeling to reflect new or evolving safety information under 21 C.F.R. § 814.39(d), and to submit a new PMA under § 814.39(a) when the cumulative effect of device modifications materially altered the safety or effectiveness of the system. Medtronic failed to comply with each of these obligations.

34. Plaintiff does not seek to challenge the FDA's authority to regulate medical devices. Rather, Plaintiff seeks to hold Medtronic accountable under state law for its failure to comply with parallel federal requirements, and to obtain judicial review of the FDA's regulatory

decisions as they relate to PMA P840001 and the Intellis Model 97715 device implanted in Plaintiff.

V. ALLEGATIONS REGARDING THE FDA AND THE APA

35. The FDA is responsible for implementing the statutory framework governing the approval and oversight of Class III medical devices under the FDCA, 21 U.S.C. § 301 et seq., and the Medical Device Amendments of 1976. As the agency charged with ensuring device safety and effectiveness, the FDA must evaluate new devices and device modifications to determine whether they require a new PMA or may be reviewed through the PMA supplement process.

36. The FDA originally granted Pre-Market Approval for Medtronic's spinal cord stimulator under PMA No. P840001 in 1984. Since then, the agency has approved over 400 supplements to this PMA, including the approval of the Intellis Model 97715 system through supplement S327 in June 2017. Subsequent supplements approved between 2017 and 2019 introduced additional material changes to the device's battery chemistry, firmware algorithms, charging interface, stimulation waveform modulation, labeling, and implantation tools.

37. These modifications collectively transformed the Medtronic SCS system into a materially different device from the Itrel II platform originally approved in 1984. The changes affected the device's energy source, operational interface, stimulation pattern, safety profile, and

surgical complexity, and introduced a user interface that relied on proprietary wireless telemetry and firmware-dependent control systems not present in the predicate device.

38. Under 21 C.F.R. § 814.39(a), a manufacturer must file a new PMA rather than a supplement when changes "affect safety or effectiveness" in ways that are significant. Nonetheless, the FDA allowed Medtronic to bypass this requirement by approving a series of real-time and 180-day supplements, often without convening expert advisory panels or requiring Medtronic to submit new clinical trial data.

39. By approving the Intellis system and its subsequent modifications through successive PMA supplements, the FDA departed from its statutory and regulatory obligations. These decisions constitute "final agency action" under 5 U.S.C. § 704 and are reviewable under the APA, 5 U.S.C. §§ 702–706.

40. The FDA's approval of the Intellis Model 97715 and its post-2017 PMA supplements was arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A) and an abuse of discretion, insofar as the agency failed to consider the cumulative impact of Medtronic's device modifications, failed to require clinical validation of the modified system, and failed to ensure that the safety and efficacy of the modified device matched or exceeded that of the original Itrel II device.

41. The FDA's failure to require Medtronic to file a new PMA in light of significant cumulative modifications also violated 21 C.F.R. § 814.39(a), which governs the threshold for when a new PMA is necessary. The agency's continued approval of Medtronic's supplements without new trials or safety review undermined the public health purpose of the PMA framework and deprived patients and providers of necessary risk disclosures.

42. Under the APA, 5 U.S.C. §§ 701–706, federal courts are authorized to review final agency actions, including agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. See 5 U.S.C. §§ 706(1), 706(2)(A)–(D); *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

43. Plaintiff brings this claim against the FDA under the APA for declaratory and injunctive relief. Plaintiff seeks a declaration that the FDA's approval of the post-2017 PMA supplements for the Intellis Model 97715 was unlawful under the APA and 21 C.F.R. § 814.39, and requests an injunction directing the agency to re-review those supplements and determine whether a new PMA application is required.

44. Plaintiff does not seek monetary relief from the FDA and does not challenge the agency's general rulemaking authority. Instead, Plaintiff seeks limited judicial review of final agency action that directly and adversely affected his legal rights and physical health by enabling the

distribution of a materially modified Class III medical device without proper clinical evaluation or public disclosure.

VI. PLAINTIFF-SPECIFIC FACTS AND DEVICE IMPLANTATION HISTORY

45. Plaintiff Dilly Anderson, also known as Dilman Anderson, is a natural person and resident of Cadiz, Kentucky. At all relevant times, Mr. Anderson reasonably relied on the representations of his treating physicians and the representations made by Medtronic regarding the safety, efficacy, and regulatory status of the Intellis spinal cord stimulator system.

46. On May 30, 2018, Mr. Anderson underwent surgical implantation of the Medtronic Intellis SCS system, Model 97715, at Mercy Health – Lourdes Hospital in Paducah, Kentucky. The procedure was performed by Dr. Jonathan Couch of Lourdes Pain Management, with support and intraoperative participation by a Medtronic field representative identified as “Roy Brown.”

47. The permanent implant followed a short trial period with an externalized Medtronic SCS system. At the time of the permanent procedure, neither Mr. Anderson nor Dr. Couch was informed of the substantial post-approval modifications to the Intellis device or the regulatory pathway by which those changes had been implemented. Mr. Anderson was also not advised that his implanted system differed

materially from the Itrel II system originally reviewed and approved by the FDA.

48. In the months following implantation, Mr. Anderson began experiencing significant complications including electric shocks, worsening low back and extremity pain, and reduced efficacy of the system. By May 2019, within a year of the implant, he also developed urinary incontinence, which required medical evaluation and treatment. These symptoms are consistent with those reported in adverse event filings related to Model 97715 in the MAUDE database.

49. Despite these ongoing complications, the device remains implanted. Mr. Anderson continues to experience persistent pain, diminished quality of life, and a lack of therapeutic benefit from the Intellis system. At no time did Medtronic disclose that the modifications approved through PMA supplements had not been validated through clinical trials or subjected to renewed FDA safety review.

50. Mr. Anderson would not have consented to implantation of the Intellis system had he been informed of the device's untested post-market configuration, the volume of adverse events associated with Model 97715, or the fact that the system had evolved substantially from the FDA-approved predicate without full premarket scrutiny.

51. The version of the Intellis system ultimately implanted in Plaintiff differed materially from the externalized trial unit. Among other

discrepancies, the permanent device introduced battery behaviors, stimulation delivery patterns, and user interface dynamics not observed during the short-term trial period. These material differences directly contributed to the post-implantation complications experienced by Plaintiff and were not disclosed prior to the permanent procedure.

52. Following implantation, Plaintiff repeatedly reported to his treating physician and to Medtronic field representatives that the device was not delivering the promised pain relief and was instead causing new and worsening symptoms, including painful electrical sensations and urinary dysfunction. Despite these reports, Plaintiff was told that the device was functioning normally. No diagnostic testing was performed by Medtronic representatives, and no disclosures were made about the existence of similar complications in other patients or the possibility that firmware or design changes contributed to the adverse outcomes.

53. By mid-2019, Plaintiff was advised to turn off the Intellis system entirely. The device remained implanted but inactive, and continued to cause pain and interference with adjacent anatomical structures. Medtronic did not recommend removal or offer support, nor did it disclose that the device had undergone significant post-approval changes without clinical testing or full FDA safety review.

VII. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

54. At all relevant times, Medtronic actively marketed and promoted its Intellis Model 97715 system to physicians and the public as an FDA-approved spinal cord stimulator that had been shown to be safe and effective through agency review. These representations failed to disclose that the device had undergone extensive, cumulative modifications since its original approval under PMA P840001 in 1984, and that these changes were implemented without new clinical trials or panel-track review.

55. Medtronic's marketing materials, training presentations, sales representative scripts, and labeling materials did not disclose that the Intellis system was based on post-2017 modifications that materially altered the device's design, firmware, charging interface, and patient-control algorithms. Nor did Medtronic provide comparative safety data showing whether the modified system remained as safe or effective as the original Itrel II platform.

56. Medtronic maintained a field representative program through which company employees—often referred to by physicians and patients as "Medtronic reps"—were physically present in operating rooms during device implantation and programming. These representatives functioned as clinical advisors despite lacking medical licenses and routinely provided intraoperative recommendations on lead placement, device anchoring, and programming parameters.

57. In Mr. Anderson's case, a Medtronic field representative was present during trial and permanent implantation and participated in programming and patient education. Neither the representative nor Medtronic disclosed the extent of post-market modifications to the system or the absence of clinical validation for the device configuration being implanted.

58. Through its field personnel, sales channels, and labeling, Medtronic held itself out as possessing superior knowledge of the device's performance and safety profile. This created a special duty to disclose material risks that were known or knowable through internal adverse event monitoring, complaint tracking, and regulatory correspondence.

59. Medtronic breached this duty by failing to disclose that its firmware modifications, energy delivery patterns, and device interface had contributed to a growing number of patient complaints and injuries—including those involving battery failure, painful shocks, stimulation loss, lead migration, and loss of efficacy.

60. Additionally, Medtronic failed to report certain adverse events and product issues to the FDA as required by 21 C.F.R. Part 803. In many instances, adverse event descriptions were incomplete, delayed, or internally coded in a manner that obscured the true nature of the malfunction or injury.

61. These omissions deprived the FDA, implanting physicians, and patients of material safety information that would have altered the risk-benefit analysis associated with use of the Intellis system. Plaintiff and his physician were thereby denied the ability to make a fully informed decision based on complete and accurate information.

62. The injuries sustained by Mr. Anderson were the foreseeable result of Medtronic's failure to comply with federal regulatory duties, its misrepresentations and omissions regarding the safety and effectiveness of the Intellis system, and its unauthorized participation in medical decision-making through unlicensed personnel.

VIII. CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

Against Medtronic, Inc.
(KRS § 411.300 et seq.; Restatement (Second) of Torts § 402A; 21 C.F.R. Part 820; *Lohr v. Medtronic*, 518 U.S. 470 (1996); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011))

63. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

64. At all relevant times, Medtronic was engaged in the business of designing, manufacturing, marketing, labeling, and selling spinal cord stimulator systems, including the Intellis Model 97715 implanted in Plaintiff.

65. Medtronic owed a duty to manufacture its spinal cord stimulator devices in conformity with applicable design specifications, regulatory requirements, and industry standards so as to render them reasonably safe for their intended use.

66. The Intellis system implanted in Plaintiff was defectively manufactured. The device, as constructed and assembled, deviated from Medtronic's design specifications and from other units in the same product line, resulting in an unreasonably dangerous condition at the time it left Medtronic's control.

67. The manufacturing defect included, but was not limited to, improper assembly, defective battery control firmware, flawed charging telemetry integration, and defective anchoring or lead stabilization mechanisms.

68. These defects rendered the device substantially more likely to cause electrical shocks, charging failures, lead migration, and loss of therapeutic efficacy.

69. The manufacturing defects directly and proximately caused Plaintiff's injuries, including severe pain, worsening neurologic symptoms, urinary incontinence, and diminished quality of life.

70. Medtronic knew or should have known that devices with such defects posed a foreseeable risk of serious injury and failed to adequately inspect, test, or remediate these conditions before distribution.

71. Plaintiff's injuries were not the result of misuse or negligence by the implanting surgeon or Plaintiff himself. The device failed during normal and foreseeable use.

72. As a direct and proximate result of Medtronic's manufacturing defect, Plaintiff suffered injuries and damages including past and future medical expenses, pain and suffering, emotional distress, and loss of enjoyment of life.

COUNT II – STRICT PRODUCTS LIABILITY: FAILURE TO WARN

Against Medtronic, Inc.

- (KRS § 411.300 et seq.; Restatement (Second) of Torts § 402A, Comment j; 21 C.F.R. §§ 803.50, 814.39, 814.82; *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010); *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc))

73. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

74. At all relevant times, Medtronic designed, manufactured, labeled, marketed, and distributed the Intellis Model 97715 spinal cord stimulator system, which was implanted in Plaintiff on May 30, 2018.

75. Medtronic had a duty to provide accurate, adequate, and timely warnings and instructions regarding the risks associated with its device, including any hazards known or reasonably knowable in light of scientific and medical knowledge available at the time of manufacture, marketing, distribution, or sale.

76. The Intellis system presented known or reasonably foreseeable risks, including but not limited to: painful electrical shocks, lead migration, premature battery failure, stimulation failure, worsening of preexisting pain, and neurologic complications such as urinary incontinence.

77. These risks were not adequately disclosed in the product labeling, Instructions for Use (IFU), training materials, or marketing documents provided to physicians and patients. Nor did Medtronic update its warnings to reflect the known post-market performance of the device as revealed by internal complaints, field reports, and adverse events submitted to the FDA under 21 C.F.R. Part 803.

78. Medtronic was aware, or should have been aware, that the cumulative modifications made to the Intellis system through post-2017 PMA supplements materially altered the risk profile of the device. Despite this, Medtronic failed to provide physicians and patients with updated warnings or to advise that the device's safety and effectiveness had not been validated through new clinical trials.

79. Medtronic also failed to disclose to physicians or the public that the Intellis system had been approved via successive supplements to PMA P840001 without panel-track review, without clinical testing of the revised configurations, and without updated labeling reflecting device evolution and new failure modes.

80. Medtronic had superior knowledge of the device's design history, material changes, and performance metrics. As such, Medtronic owed a heightened duty to ensure that known risks were disclosed in a manner reasonably calculated to reach prescribing physicians and end users.

81. Medtronic breached its duty by omitting material risk information and by actively misrepresenting the safety and efficacy of the Intellis system through its sales representatives, marketing campaigns, and physician training programs.

82. As a direct and proximate result of Medtronic's failure to warn, Plaintiff received a device whose actual risks far exceeded those disclosed at the time of implantation. Plaintiff suffered physical injuries, pain, diminished therapeutic benefit, and psychological distress that would likely have been avoided had adequate warnings been provided.

83. Plaintiff is entitled to recover damages under applicable law, including compensatory damages for personal injuries, pain and suffering, emotional distress, and the costs of future medical care.

COUNT III – NEGLIGENCE PER SE: FEDERAL REGULATORY VIOLATIONS

Against Medtronic, Inc.

(KRS § 446.070; 21 C.F.R. §§ 803.50, 820.198, 814.39(a), 814.82(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011))

84. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

85. Kentucky law recognizes claims for negligence per se where a person violates a statute or regulation designed to protect the public, and where that violation results in injury to a member of the class the law was intended to protect. See KRS § 446.070.

86. Medtronic was required to comply with multiple federal regulations governing the design, manufacture, labeling, post-market surveillance, and adverse event reporting of Class III medical devices, including the FDA regulations under 21 C.F.R. Parts 803, 814, and 820.

87. These federal regulations were enacted to protect consumers like Plaintiff from unreasonably dangerous medical devices and to ensure that serious risks are identified, disclosed, and mitigated through ongoing regulatory oversight.

88. Medtronic violated one or more of these federal regulations, including:

a. Failing to submit complete and timely adverse event reports under 21 C.F.R. § 803.50;
b. Failing to investigate and resolve post-market complaints as required by 21 C.F.R. § 820.198;
c. Failing to file a new PMA despite material cumulative changes to the device, in violation of 21 C.F.R. § 814.39(a); and

d. Failing to comply with post-approval conditions required under 21 C.F.R. § 814.82(a), including updated labeling and risk disclosure obligations.

89. In addition to the above, Medtronic violated multiple provisions of the FDA's Current Good Manufacturing Practices (cGMPs) codified at 21 C.F.R. Part 820. These include:

a. Failure to validate software and waveform design changes under § 820.30(g);
b. Failure to adequately control and monitor battery manufacturing processes under § 820.75;
c. Failure to investigate and correct known device failures through its Corrective and Preventive Action (CAPA) system under § 820.100; and
d. Failure to integrate post-market complaint data into product redesign, labeling updates, and adverse event reporting systems as required by § 820.198.

90. These failures were particularly egregious in the context of firmware-dependent control systems that were not present in the predicate device and introduced new and untested failure modes requiring regulatory reassessment.

91. These cGMP duties are non-discretionary, were enacted to protect patient safety, and constitute binding regulatory obligations. Medtronic's violations of these provisions support Plaintiff's state-law claims for negligence per se and are not preempted by federal law.

92. These regulatory violations constituted breaches of duties owed to Plaintiff under both federal law and parallel Kentucky common law principles of care, as recognized in cases permitting parallel claims that do not rely exclusively on FDCA enforcement.

93. Plaintiff's injuries were the foreseeable result of Medtronic's failure to comply with these binding regulatory requirements. The harms suffered by Plaintiff—chronic pain, electrical shocks, neurologic injury, and lack of efficacy—are of the kind the violated regulations were designed to prevent.

94. Plaintiff is a member of the class of persons the FDA's medical device regulations were intended to protect. Medtronic's violations of those regulations, therefore, constitute actionable negligence per se under Kentucky law.

95. As a direct and proximate result of Medtronic's regulatory violations, Plaintiff suffered physical and economic damages for which Medtronic is liable under the doctrine of negligence per se.

96. Plaintiff's claims are based on Kentucky and Minnesota duties that parallel federal regulatory obligations, including cGMPs and FDA-mandated adverse event reporting. These claims do not exist solely by virtue of the FDCA and are therefore not preempted under *Riegel v. Medtronic* or *Buckman Co. v. Plaintiffs' Legal Committee*.

COUNT IV – BREACH OF EXPRESS WARRANTY

Against Medtronic, Inc.

(KRS § 355.2-313; U.C.C. § 2-313; Minn. Stat. § 336.2-313; Restatement (Second) of Contracts § 2; In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009))

97. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

98. At all relevant times, Medtronic expressly warranted, through its labeling, promotional materials, sales representatives, training resources, and direct communications with physicians, that the Intellis spinal cord stimulator system was safe, effective, and FDA-approved for the treatment of chronic intractable pain of the trunk and limbs.

99. These representations were made with the intent to induce reliance by physicians, healthcare providers, and patients—including Plaintiff—and were material to the decision to undergo permanent implantation of the Intellis system.

100. Medtronic's representations included specific affirmations of fact and promises regarding the device's safety, longevity, technological superiority, and clinical benefit, including:

a. That the Intellis system had been reviewed and approved by the FDA through a rigorous safety process;

b. That the device was the "smallest implantable neurostimulator available," with improved recharge time and stimulation efficiency;

c. That it delivered "consistent, long-term pain relief" based on robust clinical support; and

d. That it incorporated proprietary software and waveform technology proven to enhance patient outcomes.

101. These affirmations and descriptions formed part of the basis of the bargain for Plaintiff's implantation and constituted express warranties under Kentucky and Minnesota law.

102. At the time Medtronic made these representations, the company failed to disclose that the Intellis system had undergone significant post-market modifications under PMA P840001, that those modifications had not been validated through clinical trials, and that adverse event reports were accumulating regarding the very risks concealed from labeling and training materials.

103. The Intellis system ultimately implanted in Plaintiff failed to perform in accordance with Medtronic's express warranties. Rather than delivering safe and effective neuromodulation therapy, the device caused electric shocks, pain aggravation, and new-onset neurologic dysfunction.

104. Medtronic breached its express warranties by supplying a product that did not conform to the descriptions, affirmations, and promises made prior to Plaintiff's implantation.

105. As a direct and proximate result of this breach, Plaintiff suffered the injuries and damages described herein, including physical

harm, mental distress, diminished therapeutic benefit, and the need for future medical treatment.

COUNT V – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE

Against Medtronic, Inc.
(KRS §§ 355.2-314, 355.2-315; Minn. Stat. §§ 336.2-314, 336.2-315; U.C.C. §§ 2-314, 2-315; Restatement (Second) of Contracts §§ 235, 351; In re Digitek Prod. Liab. Litig., 2010 WL 2102330 (S.D. W. Va. 2010))

106. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

107. At all relevant times, Medtronic was a merchant with respect to spinal cord stimulation systems, including the Intellis Model 97715. Medtronic regularly sold such devices for implantation and advertised their clinical use to physicians and patients.

108. Medtronic impliedly warranted that the Intellis system was merchantable and fit for the ordinary purposes for which such neuromodulation devices are used—namely, to provide safe, effective, and long-term pain relief for patients suffering from chronic intractable pain of the trunk and/or limbs.

109. Medtronic also knew or had reason to know that Plaintiff and his treating physician were relying on Medtronic's expertise, guidance, and representations regarding the selection and suitability of the Intellis system for Plaintiff's particular medical condition.

110. Plaintiff's physician, relying on Medtronic's express and implied assurances, selected the Intellis system for permanent implantation in Plaintiff on May 30, 2018.

111. The Intellis system implanted in Plaintiff was not of merchantable quality and was not fit for its intended or represented purpose. The device failed to deliver effective neuromodulation, resulted in painful shocks, exacerbated Plaintiff's underlying symptoms, and introduced new complications including urinary dysfunction.

112. These failures were the direct result of post-market modifications made to the system—particularly its battery controller firmware, stimulation software, and recharging hardware—that were neither tested in new clinical trials nor disclosed to Plaintiff or his physician.

113. The cumulative changes to the device architecture and programming parameters rendered the implanted system materially different from its original predicate and materially unfit for its represented purpose. These changes, along with Medtronic's failure to disclose adverse performance data, constituted a breach of the implied warranties of merchantability and fitness.

114. As a direct and proximate result of Medtronic's breach of these implied warranties, Plaintiff suffered the injuries and damages previously

described, including physical pain, mental anguish, diminished efficacy of treatment, and the need for ongoing medical intervention.

COUNT VI – NEGLIGENCE

Against Medtronic, Inc.

(KRS § 411.182; Minn. Stat. § 604.01; Restatement (Second) of Torts §§ 388, 395, 398, 402A; *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010); *Hill v. Kone, Inc.*, 602 F. Supp. 2d 1207 (D. Minn. 2009))

115. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

116. At all relevant times, Medtronic owed Plaintiff a duty to exercise reasonable care in the design, manufacture, labeling, marketing, sale, and post-market monitoring of its spinal cord stimulation systems, including the Intellis Model 97715.

117. This duty included the obligation to ensure that the device was free from dangerous defects, that it was adequately tested before and after approval, that it conformed to regulatory standards, and that any emerging risks or malfunctions were promptly disclosed to physicians and patients.

118. Medtronic breached these duties by, among other things:

a. Designing a device architecture and firmware system that introduced new risks without sufficient testing; specifically, implementing firmware-dependent control systems not present in the original predicate device, thereby creating new risk pathways without adequate validation or disclosure;

b. Manufacturing and distributing Intellis units with battery and charging defects likely to result in pain flare-ups, electrical shocks, or lead dysfunction;
c. Failing to conduct adequate clinical validation studies following cumulative device changes approved through successive PMA supplements;
d. Omitting known risks and complications from product labeling and training resources;
e. Failing to report or properly investigate adverse events, complaints, and performance anomalies as required by 21 C.F.R. §§ 803.50 and 820.198; and
f. Encouraging unlicensed field personnel to influence intraoperative decisions and postoperative care without ensuring informed consent or independent medical judgment.

119. Medtronic knew or should have known that these acts and omissions created an unreasonable risk of harm to patients such as Plaintiff, particularly in light of internal adverse event data, MAUDE reports, and device complaints from the field.

120. Medtronic's breaches of duty were a direct and proximate cause of Plaintiff's injuries, including his physical pain, neurological decline, loss of therapeutic benefit, emotional distress, and the need for continuing medical care.

121. Plaintiff is entitled to recover damages for all injuries and losses proximately caused by Medtronic's negligence under applicable state law.

COUNT VII – NEGLIGENT MISREPRESENTATION

Against Medtronic, Inc.
(*Presnell Constr. Managers, Inc. v. EH Constr., LLC*, 134 S.W.3d 575 (Ky. 2004); *Williams v. Smith*, 820 N.W.2d 807 (Minn. 2012); Restatement (Second) of Torts § 552; *In re Medtronic, Inc. Implantable Defibrillators Prod. Liab. Litig.*, 623 F. Supp. 2d 1054 (D. Minn. 2009))

122. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

123. At all relevant times, Medtronic made representations concerning the safety, efficacy, clinical validation, and FDA approval status of the Intellis spinal cord stimulator system. These representations were made through product labeling, patient brochures, direct physician marketing, industry publications, and the statements of field representatives.

124. Medtronic represented that the Intellis system was a clinically tested, FDA-approved device designed to provide safe, long-term pain relief and that it had undergone rigorous premarket evaluation and post-approval monitoring to ensure patient safety.

125. Medtronic further represented, implicitly and explicitly, that the Intellis system implanted in Plaintiff was materially equivalent to the

version originally approved under PMA P840001 and that it conformed to all current standards of safety and effectiveness.

126. These representations were false or misleading when made. Medtronic failed to disclose that:

a. The Intellis Model 97715 system had undergone significant post-approval modifications under multiple PMA supplements;
b. These changes were not subject to new clinical trials or panel-track PMA review;
c. Adverse events associated with the modified device were accumulating in Medtronic's internal complaint systems and the FDA's MAUDE database; and
d. The safety and effectiveness of the cumulative changes had not been validated or disclosed to implanting physicians.

127. Medtronic failed to exercise reasonable care in ascertaining the truth of these representations, despite having exclusive access to post-market performance data, adverse event reports, engineering change logs, and regulatory correspondence.

128. Plaintiff and his implanting physician reasonably relied on Medtronic's misrepresentations and omissions when deciding to proceed with implantation of the Intellis system in May 2018.

129. Had Plaintiff or his physician known the true nature and risks of the modified device, including its failure to undergo renewed clinical

testing, they would not have selected or consented to implantation of the Intellis system.

130. As a direct and proximate result of Medtronic's negligent misrepresentations, Plaintiff suffered the injuries described herein, including avoidable pain, neurological harm, loss of benefit of the device, and ongoing need for medical treatment.

COUNT VIII – FRAUDULENT CONCEALMENT

Against Medtronic, Inc.

(*Miller v. Reminger Co., LPA*, 569 S.W.3d 232 (Ky. 2019); *Davis v. Re-Trac Mfg. Corp.*, 149 N.W.2d 37 (Minn. 1967); Restatement (Second) of Torts §§ 550–551; *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 484 F. Supp. 2d 973 (D. Minn. 2007))

131. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

132. At all relevant times, Medtronic had superior knowledge of the design, approval history, and post-market performance of the Intellis spinal cord stimulator system, including the cumulative changes implemented through PMA supplements and the growing number of adverse events associated with those changes.

133. Medtronic intentionally concealed material facts from Plaintiff and his physician regarding the true regulatory status and safety profile of the Intellis system, including:

a. That the Intellis system had been materially altered from the original PMA-approved configuration;

b. That the FDA had not required Medtronic to submit new clinical trial data to validate these changes;
c. That adverse event reports describing electric shocks, pain exacerbation, stimulation failure, and neurologic injury were associated with the post-2017 configuration of the device; and
d. That internal data revealed increasing reports of complications following implantation of the Intellis Model 97715.

134. Medtronic had a duty to disclose these material facts because:

a. It had exclusive access to adverse event and complaint data not available to physicians or the public;
b. It voluntarily undertook to provide information to physicians and patients and thereby created a duty to speak truthfully; and
c. The concealed facts were essential to informed consent and materially affected the risk-benefit analysis for permanent implantation.

135. Medtronic acted with intent to deceive, suppressing material information for the purpose of preserving market share and avoiding regulatory scrutiny of the device's evolution and adverse performance data.

136. Plaintiff and his physician reasonably relied on Medtronic's incomplete disclosures and misleading assurances when deciding to proceed with implantation of the device.

137. Medtronic's fraudulent concealment directly and proximately caused Plaintiff's injuries by depriving him of the opportunity to make an informed decision regarding his care and exposing him to a device with undisclosed and unvalidated risks.

138. As a result of this fraudulent concealment, Plaintiff suffered harm including avoidable physical injury, loss of therapeutic benefit, emotional distress, and the need for continued medical treatment.

COUNT IX – VIOLATION OF THE KENTUCKY CONSUMER PROTECTION ACT

Against Medtronic, Inc.

(KRS § 367.170 et seq.; KRS § 367.220; *Stevens v. Motorists Mut. Ins. Co.*, 759 S.W.2d 819 (Ky. 1988); *Corder v. Ford Motor Co.*, 869 F. Supp. 2d 835 (W.D. Ky. 2012))

139. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

140. The Kentucky Consumer Protection Act (KCPA), KRS § 367.170, prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce."

141. Medtronic is a "person" engaged in "trade or commerce" as defined by KRS § 367.110(1), and its activities in marketing, selling, and distributing spinal cord stimulator devices—including the Intellis Model 97715—are governed by the Act.

142. Medtronic violated the KCPA by engaging in unfair, deceptive, and misleading acts and omissions, including:

a. Marketing the Intellis system as safe, effective, and FDA-approved without disclosing the cumulative post-market modifications made under PMA supplements;

b. Failing to disclose known adverse events and internal risk data associated with the modified system;

c. Representing that the system's performance was supported by clinical data, when in fact no new clinical trials had been conducted for the post-2017 configuration; and

d. Using field representatives to promote implantation without ensuring that complete and accurate product risk information was conveyed to physicians and patients.

143. These representations were made with the intent to induce consumers—including Plaintiff and his physician—to purchase, rely upon, and accept implantation of the Intellis system.

144. Plaintiff, as the end user and ultimate consumer of the device, is entitled to protection under the KCPA and to bring a private right of action for damages under KRS § 367.220.

145. Plaintiff relied on Medtronic's deceptive practices when agreeing to permanent implantation of the device. Had he known the truth regarding the device's approval history and performance risks, he would not have consented to the procedure.

146. As a direct and proximate result of Medtronic's violations of the KCPA, Plaintiff suffered harm including physical injury, loss of therapeutic benefit, emotional distress, and the need for further medical intervention.

147. Plaintiff is entitled to all relief available under the Act, including actual damages, statutory damages, attorney's fees, and costs.

COUNT X – NEGLIGENCE PER SE: UNAUTHORIZED PRACTICE OF MEDICINE

Against Medtronic, Inc.

(KRS § 311.560; Minn. Stat. § 147.081; KRS § 446.070; Restatement (Second) of Torts § 286; *Hill v. Kone, Inc.*, 602 F. Supp. 2d 1207 (D. Minn. 2009))

148. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

149. At all relevant times, Medtronic deployed field representatives—sometimes referred to as "clinical specialists" or "device consultants"—to assist with intraoperative procedures involving the implantation and programming of its spinal cord stimulator systems, including the Intellis Model 97715 implanted in Plaintiff.

150. These representatives were not licensed physicians, surgeons, or healthcare providers in the state of Kentucky or Minnesota. Nonetheless, they were present during Plaintiff's trial and permanent implantation procedures and provided technical guidance to the operating physician regarding lead placement, anchor selection, stimulation parameters, and device programming.

151. In addition, Medtronic representatives played a material role in patient education, postoperative troubleshooting, and programming of stimulation parameters without proper oversight or medical licensure.

152. Under KRS § 311.560, it is unlawful for any person to engage in the practice of medicine in Kentucky without a license issued by the Kentucky Board of Medical Licensure. Similar prohibitions exist under Minnesota law at Minn. Stat. § 147.081.

153. Medtronic's representatives, acting on behalf of the company, violated this statutory prohibition by engaging in clinical decision-making, patient-specific programming, and therapeutic consultations without being authorized medical professionals.

154. Medtronic is vicariously liable for the conduct of its representatives and is directly liable for creating, endorsing, and encouraging a business model that involved the unauthorized practice of medicine as a core feature of its SCS product support.

155. These violations of KRS § 311.560 and Minn. Stat. § 147.081 constitute negligence per se under Kentucky law, as codified in KRS § 446.070, and Minnesota law. Plaintiff is a member of the class of persons intended to be protected by these statutes—i.e., patients receiving medical care from licensed professionals—and the harms suffered were the type the statutes were designed to prevent.

156. As a direct and proximate result of Medtronic's violations of these statutory duties, Plaintiff suffered physical injuries, loss of therapeutic benefit, and emotional distress caused by improper device

programming, inadequate postoperative support, and a lack of informed medical decision-making.

COUNT XI – VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT (APA)

Against the U.S. Food and Drug Administration
(5 U.S.C. §§ 702–706; 21 U.S.C. §§ 360c, 360e; 21 C.F.R. §§ 814.39, 814.82; *Loper Bright Enters. v. Raimondo*, 603 U.S. 368 (2024); *Bennett v. Spear*, 520 U.S. 154 (1997))

157. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

158. The APA authorizes judicial review of final agency action. See 5 U.S.C. §§ 702, 704, 706. The APA requires courts to set aside agency actions that are arbitrary, capricious, an abuse of discretion, contrary to law, or in excess of statutory authority. See 5 U.S.C. § 706(2)(A)–(C).

159. The FDA is a federal agency subject to the APA. Under the FDCA, it is required to approve a new PMA application when cumulative changes to a Class III device affect its safety or effectiveness in a material way. See 21 C.F.R. § 814.39(a). The agency must also enforce compliance with post-approval conditions under § 814.82.

160. FDA approved PMA P840001 in 1984 for Medtronic's Itrel II spinal cord stimulator. Between 1984 and 2018, Medtronic implemented over 400 PMA supplements, including major functional and structural changes through Supplements S327, S331, S345, S354, and S359. These

changes introduced new hardware, firmware, waveform modulation, battery chemistry, surgical interfaces, and wireless programming features.

161. The FDA approved each of these cumulative changes through expedited supplement review processes—without convening an advisory panel, without requiring new clinical trial data, and without subjecting the modified device to renewed risk analysis.

162. The FDA's decision to allow these significant post-2017 modifications under PMA supplement review—rather than requiring a new PMA—violated its statutory duty under the FDCA and its own regulation, 21 C.F.R. § 814.39(a). These decisions were arbitrary, capricious, and contrary to law within the meaning of § 706(2)(A), and were made in excess of statutory authority under § 706(2)(C).

163. Under the Supreme Court's decision in *Loper Bright Enterprises. v. Raimondo*, 603 U.S. 368 (2024), this Court owes no deference to the FDA's interpretation of § 814.39(a) or the statutory boundaries of PMA supplement authority. The Court may independently assess whether the FDA exceeded its regulatory authority in allowing successive unvalidated device changes under the PMA supplement framework.

164. These decisions constitute final agency action under 5 U.S.C. § 704. Plaintiff is directly and adversely affected by these approvals because he was implanted with a version of the Intellis device that materially

departed from the original Itrel II system, without clinical validation, adequate risk disclosure, or informed consent.

165. Plaintiff seeks judicial review of the FDA's unlawful approvals and declaratory relief to remedy the agency's violation of federal law.

WHEREFORE, Plaintiff respectfully requests that the Court:

a. **Declare** that the FDA's approval of the post-2017 PMA supplements to P840001, which allowed marketing of the Intellis Model 97715 without a new PMA, violated the APA and 21 C.F.R. § 814.39(a);
b. **Declare** that Plaintiff's state-law claims against Medtronic are not subject to express or implied preemption under the FDCA or MDA, because the device implanted in Plaintiff was materially modified beyond the scope of the original PMA and not subject to full FDA safety review;
c. **Declare** that the FDA's continued acceptance of cumulative, unvalidated device modifications through the PMA supplement pathway was contrary to law and in excess of statutory authority;
d. **Declare** that the FDA's decision constituted arbitrary and capricious agency action within the meaning of 5 U.S.C. § 706(2);
e. **Enjoin the FDA** from approving future PMA supplements to P840001 for the Intellis system or any materially modified successor device without requiring a new PMA or clinical data; and
f. **Order such other and further relief** as the Court deems just and proper under the APA.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor and against Defendant Medtronic, Inc., and, with respect to Count X, against the United States Food and Drug Administration, 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 KRS § 367.220 and any other applicable consumer protection statutes;
c. **Punitive or exemplary damages**, as allowed by law, based on Defendant Medtronic's willful, malicious, and/or reckless disregard for the safety and rights of Plaintiff and the public;
d. **Declaratory and injunctive relief** against the FDA as set forth in Count X, pursuant to 5 U.S.C. §§ 702–706;
e. **Pre-judgment and post-judgment interest** as provided by law;
f. **The costs** of this action; and

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

J

JURY DEMAND

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

Dated: May 2, 2025

Respectfully submitted,

/s/ Rachel P. Richardson
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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

DILLY ANDERSON

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Richard Hood
The Wilhite Law Firm
1600 N. Ogden Street

DEFENDANTS

MEDTRONIC, INC.,
MEDTRONIC USA, INC., and
UNITED STATES FOOD AND DRUG ADMINISTRATION

County of Residence of First Listed Defendant Anoka, MN
(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

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

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

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

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

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 involving injury to Plaintiff caused by Defendants' Medical Device

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
5/2/2025

SIGNATURE OF ATTORNEY OF RECORD
/s/ Rachel Richardson

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.

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

UNITED STATES DISTRICT COURT

for the

District of Minnesota

DILLY ANDERSON

Plaintiff(s)

v.

MEDTRONIC, INC., and
UNITED STATES FOOD AND DRUG ADMINISTRATION

Defendant(s)

Civil Action No. 0:25-01967

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432

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: Richard Hood
The Wilhite Law Firm
1600 N. Ogden Street
rhood@wilhitelawfirm.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. 0:25-01967

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 $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

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

District of Minnesota

DILLY ANDERSON

Plaintiff(s)

v.

MEDTRONIC, INC., and
UNITED STATES FOOD AND DRUG ADMINISTRATION

Defendant(s)

Civil Action No. 0:25-cv-01967

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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: Richard Hood
The Wilhite Law Firm
1600 N. Ogden Street
rhood@wilhitelawfirm.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. 0:25-cv-01967

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❒ 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 $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

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: