IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW MEXICO

RON YUSNUKIS,	Case No.:	1:24-cv-355
Plaintiff		
v.		
NEVRO CORPORATION,		
Defendant.		

COMPLAINT

Plaintiff, by and through his undersigned counsel, brings this Complaint at Law against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the tortious conduct of the Defendants named herein related to the implantation and subsequent injurious failure of the Nevro HF10 spinal cord stimulation device ("SCS" or "product"). As a result of the wrongful conduct enumerated herein, Plaintiff Ron Yusnukis suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which he may be legally entitled.

I. PARTIES & JURISDICTION

2. Plaintiff Ron Yusnukis ("Plaintiff") is, and was, at all relevant times, a citizen and resident of New Mexico and the United States.

- 1. Defendant, Nevro Corporation (hereinafter "Nevro"), now is, and at all times relevant to this action was, a Delaware Corporation which has its principal place of business and headquarters in the State of California.
- 2. Nevro has conducted business and derived substantial revenue from within New Mexico and has sufficient minimum contacts and purposefully avail themselves of the New Mexico Market so as to render the exercise of jurisdiction over it by the New Mexico courts consistent with the traditional notions of fair play and substantial justice. The instant cause of action arises from and is related to Nevro's contacts with and conduct and transactions within the State of New Mexico.
- 3. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. §1965

 (a) because a substantial part of the events or omissions giving rise to the claim occurred in this

 District and each Defendant transacts business affairs and conducts activity that gave rise to the claim

 of relief in this District.

II. FACTUAL BACKGROUND

- 4. Defendant Nevro designs, manufactures, markets, and distributes the Nevro HF10 SCS, an implantable device indicated for the treatment of a limited varieties of chronic and intractable pain.
- 5. Defendant's SCS product includes an implanted Pulse Generator (IPG) and percutaneous lead wires.
- 6. The IPG is a rechargeable implantable device with 16 output channels. Each of the 16 outputs can be programmed as a cathode or an anode. The IPG is powered by a 3.6 V nominal Li-Ion rechargeable battery (single cell). It is capable of stimulating the spinal cord nerves through the electrodes of the leads connected to any combination of the output terminals, using a single current source
 - 7. The IPG component of the SCS is implanted in the patient subcutaneously, and the lead

wires are implanted and secured along predetermined locations along the patient's spinal cord.

- 8. Once implanted and operational, the SCS delivers electrical impulses to the patient's spinal cord, with the purpose of modulating the electrical pain signals which manifest in subjective patient pain.
- 8. The implantation parameters for the SCS and the magnitude of electrical stimulation delivered by it often results in repeated electrical insult to one or more branches of the vagus nerve.
- 9. The different branches of the vagus nerve, respectively, modulate such processes as esophageal motility, cardiac rhythm, bowel function, and many others.
- 10. The overstimulation caused by the design of the Nevro SCS can lead to dysmotility, arrhythmias and incontinence.
- 11. Moreover, the magnitude and duration of insult to the vagus nerve caused by the Nevro SCS can give way to a process called nociception, whereby the parasympathetic nervous system perpetuates the manifestations of the aforementioned overstimulation, rendering the complications functionally permanent.
- 12. Defendant is aware of these risks and has failed to adequately warn patients or medical providers, including those of Plaintiff.
- 13. Mr. Yusnukis underwent a trial of spinal cord stimulation in March of 2021 for the purpose of treating his chronic pain syndrome and lumbar radiculitis. At the conclusion of the trial, Mr Yusnukis reported a significant reduction of his pain.
- 14. On or about March 22, 2021, Plaintiff underwent placement of a permanent Nevro HF10 SCS by Dr. Terry Hansen.
- 15. On or about May 3, 2024, Plaintiff reported experiencing tachycardia, parasthesias, and muscular spasms to Dr. Hansen.

- 16. Following the aforementioned encounter, Plaintiff began to experience additional complications, including syncopal episodes and new onset fecal incontinence.
- 17. On or about May 10, 2021, Plaintiff underwent surgery to remove the Nevro SCS.
 - 18. At no relevant time did Plaintiff abuse or misuse his SCS or its component parts.
- 19. At all relevant times Plaintiff complied with the directives and instructions associated with use of the device, namely, those set forth in the patient user manual.
- 20. Even after removal of the SCS, Plaintiff continues to suffer from syncopal episodes and fecal incontinence due to the failure of the SCS.

COUNT ONE: STRICT PRODUCTS LIABILITY

- 21. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this Count.
- 22. Plaintiff received and utilized the SCS in a foreseeable manner as normally intended recommend, promoted, and marketed by the Defendants.
- 23. The SCS malfunctioned, causing Plaintiff's injuries, in that the SCS caused overstimulation and nerve damage.
- 24. The SCS was and is unreasonably dangerous in that, as designed and/or manufactured, it failed to perform in accordance with the PMA approval order and end user expectations when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.
- 25. The SCS was and is unreasonably dangerous and defective in design or formulation for its intended use in that, when it left the hands of the manufacturer and/or supplier, it posed a risk of serious injury which could have been reduced or avoided, *inter alia*, by

conformance with the PMA approval order and/or dissemination of a product label which was neither false nor misleading.

- 26. The SCS unit did not meet reasonable consumer expectations in that Plaintiffwas clearly an intended user, using it for its intended use, yet suffered injuries, requiring the device to be removed and returning him to a lack of relief for his chronic pain.
- 27. The SCS as manufactured and supplied by the defendants is and was defective due to inadequate warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its SCS, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendant was directly marketing and advertising; and further, Defendant continued to affirmatively promote its SCS as safe and effective and as safe and effective as its predicate device.
- 28. As a direct and proximate result of the SCS' defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future.
- 29. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff may have lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the device's defect.
- 30. By reason of the foregoing, Defendant is liable to the Plaintiff for damages as a result of its failure to warn and/or adequately warn the Plaintiffs and healthcare professionals about the increased risk of serious injury caused by their defective SCS.

WHEREFORE, Plaintiffs demand judgment against the Defendant for whatever total amount they may be entitled, together with costs of this action.

COUNT TWO: NEGLIGENCE

- 31. Plaintiffs incorporate by reference all above allegations.
- 32. At all times relevant to this cause of action, the Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the SCS.
- 33. Defendant owes a legal duty to patients such as Plaintiff to comply with the FDA requirements; failure to do so exposes them to legitimate causes of action in negligence.
- 34. The existence of a duty to exercise reasonable care in the manufacturing of a product is implied in the supplier-consumer relationship.
- 35. Defendant did not comply with its post-market obligation to report serious adverse events to the FDA, having become aware of numerous events such as those experienced by Plaintiff, depriving any opportunity to investigate a possible systemic design or manufacturing defect, or at least the provision for a warning, presumably would have been heeded by Plaintiff.
- 36. As a direct and proximate result of the SCS' defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff may have lost earnings and may continue to lose earnings into the future and has medical bills both past and future related to care because of the SCS's defects.

WHEREFORE, Plaintiffs demand judgment against the Defendant for whatever total amount they may be entitled, together with costs of this action.

JURY DEMAND

Plaintiffs demand a trial by jury on all of the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor and against Mentor, awarding Plaintiffs:

- actual or compensatory damages including pain and suffering, emotional a. distress, disfigurement, loss of consortium, past and future medical expenses, and lost wages in such amount to be determined at trial and as provided by applicable law;
- exemplary and punitive damages sufficient to punish and deter Nevro and others b. from future negligent and reckless practices;
- pre-judgment and post-judgment interest; c.
- costs including reasonable attorneys' fees, court costs, and other litigation d. expenses; and
- any other relief the Court may deem just and proper. e.

Respectfully submitted, Dated: April 12, 2024

DICKERSON OXTON, LLC.

BY: /s/ Adam M. Evans

Adam M. Evans (MO #60895) (Pro Hac Vice Application Forthcoming) Dickerson Oxton, LLC 1100 Main St., Ste. 2550 Kansas City, MO 64105 Phone: (816) 268-1960

Fax: (816) 268-1965

Email: aevans@dickersonoxton.com

Counsel for Plaintiff

JS 44 (Rev. 04/21) Case 1:24-cv-00355-SMDCIFIL COVERSHEET iled 04/12/24 Page 1 of 2

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.)

purpose of initiating the civil d	ocket sheet. (SEE INSTRUCTIONS ON NI	EXT PAGE OF THIS FO	PRM.)		
I. (a) PLAINTIFFS			DEFENDANTS		
Ron Yusnukis			Nevro Corporation		
(b) County of Residence of First Listed Plaintiff Sandoval County, I (EXCEPT IN U.S. PLAINTIFF CASES)			County of Residence of First Listed Defendant San Mateo County, CA (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.		
•	Address, and Telephone Number) n - 1200 Main St., Suite 2120, D 64105	,	Attorneys (If Known)		
II. BASIS OF JURISD	ICTION (Place an "X" in One Box Only,) III. CIT	TIZENSHIP OF PR	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff
1 U.S. Government Plaintiff	3 Federal Question (U.S. Government Not a Party)		(For Diversity Cases Only) PT n of This State	F DEF	
2 U.S. Government Defendant	X 4 Diversity (Indicate Citizenship of Parties in	ı Item III)	n of Another State	of Business In	Another State
			n or Subject of a eign Country	3 Soreign Nation	66
IV. NATURE OF SUIT	(Place an "X" in One Box Only)		(Click here for: Nature of	Suit Code Descriptions.
CONTRACT	TORTS		RFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
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	310 Airplane	nal Injury - uct Liability 690 h Care/ naceutical nal Injury tet Liability stos Personal y Product lility L PROPERTY Fraud in Lending Personal rty Damage rty Damage rty Damage rty Liability R PETITIONS Corpus: 791 Detainee ons to Vacate nce ral n Penalty 462 463 463 465 465 790 791	LABOR D Fair Labor Standards Act Labor/Management Relations Railway Labor Act Family and Medical Leave Act Other Labor Litigation Employee Retirement Income Security Act IMMIGRATION Note The Property of Standards Act Act Other Labor Description Actions Actions	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	Corrupt Organizations 480 Consumer Credit (15 USC 1681 or 1692) 485 Telephone Consumer Protection Act 490 Cable/Sat TV 850 Securities/Commodities/
A -		rom 4 Reins		1 1	
VI. CAUSE OF ACTIO	Cite the U.S. Civil Statute under w		(specify)	Transfer	Direct File
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS IS A CLASS UNDER RULE 23, F.R.Cv.P.	~	EMAND \$	CHECK YES only JURY DEMAND	if demanded in complaint: Yes No
VIII. RELATED CASI IF ANY	E(S) (See instructions): JUDGE			DOCKET NUMBER	
DATE 04/12/2024		URE OF ATTORNEY O M. Evans	F RECORD		
FOR OFFICE USE ONLY	, , , , , ,	-			
	MOUNT APPL	YING IFP	JUDGE	MAG. JU	IDGE

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.