July 31, 2024

Retropsoas Technologies, LLC
% Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry, Inc. (dba SpiTrex 3D)
1815 Aston Avenue, Suite 106
Carlsbad, California 92008

Re: K241917
Trade/Device Name: EARP Nerve Cuff Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: June 28, 2024
Received: July 1, 2024

Dear Jeffrey Brittan:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241917

Device Name
EARP Nerve Cuff Electrode

Indications for Use *(Describe)*
The EARP Nerve Cuff Electrode is used to perform localized stimulation of neural tissue and to locate, identify, and monitor spinal nerve roots during surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

DATE PREPARED
June 27, 2024

CONTACT DETAILS

Applicant	Retropsoas Technologies, LLC 34 Countryside Lane Frontenac, MO 63131 USA Telephone: 618-402-0035 Contact: Dr. Nicholas Poulos, CEO Email: npoulos@retropsoas.com
Correspondent	Jeffrey Brittan Vice President of Product Realization SpiTrex 3D (Watershed Idea Foundry, Inc. dba SpiTrex 3D) Telephone: 714-287-6780 Email: jeffbrittan@spitrexorthopedics.com

DEVICE NAME

Device Trade Name	EARP Nerve Cuff Electrode
Common Name	Surgical nerve stimulator/locator
Classification Name	Stimulator, Nerve
Regulation Number	21 CFR 874.1820
Product Code	ETN

LEGALLY MARKETED PREDICATE DEVICES

Predicate #	K230853
Predicate Trade Name	EARP Nerve Cuff Electrode
Product Code	ETN

DEVICE DESCRIPTION SUMMARY
The EARP Nerve Cuff Electrode conducts electrical signal as a component of intraoperative neuromonitoring. The EARP Nerve Cuff Electrode is used with commercially available neuromonitoring systems and does not stimulate or record signal itself. The standard connectors at the proximal end of the EARP Nerve Cuff Electrode interface with the neuromonitoring equipment and the distal cuff contacts the target tissue. The EARP Nerve Cuff Electrode is provided sterile packaged and is for single use only.

INTENDED USE / INDICATIONS FOR USE

The EARP Nerve Cuff Electrode is used to perform localized stimulation of neural tissue and to locate, identify, and monitor spinal nerve roots during surgery.

INDICATIONS FOR USE COMPARISON

There are no changes to indications for use for the subject device in comparison to the predicate device (i.e., indications for use are the same).

TECHNOLOGICAL COMPARISON

The subject device has been updated with "slimline" versions that maintain equivalent design characteristics, materials, chemical composition, and principle of operation as the predicate device, while offering nerve cuff options with smaller sizing. The smaller cuff inside diameter and width sizing options provide additional flexibility for physicians who may have patients with smaller anatomy or who prefer to use a smaller device without changing device function or performance. In addition, a manufacturability enhancement to use a single thickness for the nitinol spring component is included.

	Subject Device	***Predicate Device***	***Equiv.***
	EARP Nerve Cuff Electrode (Subject Device)	EARP Nerve Cuff Electrode (K230853)	
Indications for Use	The EARP Nerve Cuff Electrode is used to perform localized stimulation of neural tissue and to locate, identify, and monitor spinal nerve roots during surgery.	The EARP Nerve Cuff Electrode is used to perform localized stimulation of neural tissue and to locate, identify, and monitor spinal nerve roots during surgery.	Yes
Principle of Operation	Conducts signal between neuromonitoring equipment and nerve (interfaces w/ commercially available neuromonitoring systems)	Conducts signal between neuromonitoring equipment and nerve (interfaces w/ commercially available neuromonitoring systems)	Yes
Product Codes /Reg#	ETN (21 CFR 874.1820) Stimulator, Nerve	ETN (21 CFR 874.1820) Stimulator, Nerve	Yes
Duration of Use	Intraoperative (Single use)	Intraoperative (Single use)	Yes
Implanted	No (Removed after use)	No (Removed after use)	Yes
Tissue Engagement	Direct nerve contact (C-shaped cuff)	Direct nerve contact (C-shaped cuff)	Yes
Tip Contact Exposure	2mm (Strip)	2mm (Strip)	Yes
Bipolar or Monopolar?	Bipolar	Bipolar	Yes
Electrode Contact Material	Conductive metal (Platinum)	Conductive metal (Platinum)	Yes
Electrode Insulation	Polymer (Polyimide)	Polymer (Polyimide)	Yes
Cuff Material	Polymer (Silicone)	Polymer (Silicone)	Yes
Lead Length	1.8m	1.8m	Yes
Lead Wire Material	Conductive metal (Stainless steel)	Conductive metal (Stainless steel)	Yes
Lead Wire Insulation	Polymer (FEP)	Polymer (FEP)	Yes
Connector Style	1.5mm safety socket	1.5mm safety socket	Yes
Cuff Sizing	Inside diameters: 3, 4, 5, 6mm Width: 3mm Inside diameter encircling: 90%	Inside diameters: 4, 6, 8, 10mm Width: 5mm Inside diameter encircling: 85%	Yes
Nitinol Spring Thickness	Circular segment: 0.19mm Horn segment: 0.19mm	Circular segment: 0.19mm Horn segment: 0.25mm	Yes
Provided Sterile	Yes	Yes	Yes

NON-CLINICAL TESTS SUMMARY & CONCLUSIONS

Analysis of the subject device modifications verified that they would not impact function or performance. Results of this analysis demonstrated that the additional sizing options for the silicone cuff, as well as the single spring thickness manufacturability enhancement, would not affect the ability of the device to mate with the applicator tool, be applied to and maintain contact with the nerve and, or conduct neuromonitoring signal. Accordingly, the analysis supported the conclusion that the subject EARP Nerve Cuff Electrode is substantially equivalent to the predicate EARP Nerve Cuff Electrode.