October 6, 2023

Nvision Biomedical Technologies, Inc.
% Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K230853
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: September 6, 2023
Received: September 7, 2023

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,

Patrick Antkowiak -S

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

DATE PREPARED
October 4, 2023

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PROPRIETARY NAME OF SUBJECT DEVICE
EARP Nerve Cuff Electrode

COMMON NAME
Nerve Stimulator

DEVICE CLASSIFICATION
Surgical nerve stimulator/locator
(Classification Regulations: 21 CFR 874.1820, Product Codes: ETN, Class: II)

PREMARKET REVIEW
Ear, Nose, & Throat

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.

DEVICE DESCRIPTION
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.

PREDICATE DEVICE IDENTIFICATION

The subject EARP Nerve Cuff Electrode is substantially equivalent to the following predicates:

510(k) Number	*Manufacturer & Predicate Device Name*	*Predicate*
K103128	Cadwell Lab Disposable Stimulator Probes	Primary
K944061	Ad-Tech Medical Cueva Cranial Nerve Electrode	Additional

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for nerve stimulators or electrodes. The EARP Nerve Cuff Electrode was evaluated to ensure that it performed as intended and supported substantial equivalence to the predicate devices. Testing and analysis included:

- Analysis of dimensional characteristics, materials, function, and intended use
- Tensile and flexural testing (to verify mechanical integrity, continuity, isolation, and visual appearance)
- Electrical safety testing (high potential and electrical leakage per ISO 14708-1)
- Electrode lead wire performance per 21 CFR 898.12 (IEC 60601-1)
- Biocompatibility testing including cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity:

Endpoint	**Test Description**	**Conclusion**	**Pass/Fail**
Cytotoxicity (ISO 10993-5)	Elution Method (1X MEM extraction vehicle)	The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).	Pass
Sensitization (ISO 10993-10)	Maximization Sensitization Study (Polar and non-polar extraction vehicles)	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	Pass
Irritation (ISO 10993-23)	Intracutaneous Study (Polar and non-polar extraction vehicles)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.1 for the SC and SO test article extracts, respectively.	Pass
Acute Systemic Toxicity (ISO 10993-11)	Systemic Toxicity Study (Polar and non-polar extraction vehicles)	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.	Pass
Material-Mediated Pyrogenicity (USP<151>, ISO 10993-11)	Pyrogen Study - Material Mediated (Sterile non-pyrogenic saline extraction vehicle)	The total rise of rabbit temperatures during the 3 hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.	Pass

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device	*Predicate Devices*	
	EARP Nerve Cuff Electrode	Cadwell Lab Disposable Stimulator Probes	Ad-Tech Medical Cueva Cranial Nerve Electrode
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.	Cadwell Disposable Stimulator Probe is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.	The Cueva Cranial Nerve Electrode is intended for use to monitor cranial nerves during skull base type surgeries.
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)	Conducts signal between neuromonitoring equipment and nerve (interfaces w/ commercially available neuromonitoring systems)
Product Codes /Reg#	ETN (21 CFR 874.1820) Stimulator, Nerve	ETN (21 CFR 874.1820) Stimulator, Nerve	GZL (21 CFR 882.1330) Electrode, Depth
Duration of Use	Intraoperative (Single use)	Intraoperative (Single use)	Intraoperative (Single use)
Implanted	No (Removed after use)	No (Removed after use)	No (Removed after use)
Tissue Engagement	Direct nerve contact (C-shaped cuff)	Direct nerve contact (Forked tip)	Direct nerve contact (C-shaped cuff)
Tip Contact Exposure	2mm (Strip)	2mm (Balls)	~2mm (Strip)
Electrode Exposed Surface Area	15.4 - 42.6mm^2	~25.1 - 33.2mm^2	~10.4 - 14.5mm^2
Bipolar or Monopolar?	Bipolar	Bipolar and monopolar versions	Monopolar
Electrode Contact Material	Conductive metal (Platinum)	Conductive metal (Stainless Steel)	Conductive metal (Platinum)
Electrode Insulation	Polymer (Polyimide)	Polymer (PTFE)	Polymer
Cuff Material	Polymer (Silicone)	N/A	Polymer (Silicone)
Lead Length	1.8m	2.0m	1.8m
Lead Wire Material	Conductive metal (Stainless steel)	Conductive metal (Tin plated copper)	Conductive metal
Lead Wire Insulation	Polymer (FEP)	Polymer (PVC)	Polymer
Connector Style	1.5mm safety socket	1.5mm safety socket	1.5mm safety socket
Applicator Tool Length	260mm	190 to 330mm (handle & shaft)	250mm
Provided Sterile?	Yes	Yes	Yes

CONCLUSION

Based on testing and analysis of device characteristics, it can be concluded that the subject device does not raise new issues of safety compared to the predicate devices. The equivalent indications for use, technological characteristics, and performance characteristics for the EARP Nerve Cuff Electrode are assessed to be substantially equivalent to the predicate devices.