May 15, 2025

NeurAxis
℅ Dawn Norman
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K250451
Trade/Device Name: NeurAxis IB-Stim (01-1020)
Regulation Number: 21 CFR 876.5340
Regulation Name: Nonimplanted Nerve Stimulator For Functional Abdominal Pain Relief
Regulatory Class: Class II
Product Code: QHH
Dated: February 13, 2025
Received: February 18, 2025

Dear Dawn Norman:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K250451

Device Name
IB-Stim

Indications for Use *(Describe)*
The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 8-21 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS) and functional dyspepsia (FD). The IB-Stim is intended to be used for 120 hours per week, using 1 device per week for 4 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS and FD. FD patients for whom IB-Stim is indicated have also been shown to experience reduction of nausea symptoms.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
IB-Stim
May 14, 2025

Company: NeurAxis, Inc.
11611 N. Meridian St.
Suite 330
Carmel, IN 46032

Primary/Secondary Contact: Dawn N. Norman, MS
Partner MRC Global
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Kathy Remsen – Regulatory Consultant
(901) 606-4856
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Company Contact: Dr. Thomas J. Carrico, CRO

Trade Name: NeurAxis IB Stim (01-1020)

Common Name: Non-implanted nerve stimulator for functional abdominal pain relief

Classification: Class II

Regulation: 21 CFR 876.5340

Panel: Neurology

Product Code: QHH

Primary Predicate: Neuraxis IB Stim (K241533)

Device Description:
IB-Stim stimulator is a battery-operated micro-stimulation appliance weighing 5 grams designed as a disposable product for a single use. IB-Stim stimulator is placed behind the patient's ear and connected to stimulation needles on the auricle. IB-Stim stimulator offers regular therapy over several days. The appliance transmits low-frequency electric pulses.

IB-Stim is a device system that consists of a (1) percutaneous electrical nerve field stimulator (PENFS); (2) sterile multi-pin wire harness array; (3) round bandages to fasten the appliance leads, stimulator skin adhesive, alcohol swab, transparent dressing, biohazard bag, and Patient ID card; (4) tweezers; (5) surgical marker; and (6) transilluminator for use in transillumination technique that aids in needle implantation. The wire harness array

consists of 4 leads. The 1-1-1-4 configuration consists of three single-needle leads, and one 4-needle array. The transilluminator emits a light for use in the trans-illumination technique to aid the clinician in identifying the nerve bundles in the ear.

Indications for Use:
The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 8-21 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS) and or functional dyspepsia (FD). The IB-Stim is intended to be used for 120 hours per week, using 1 device per week for 4 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS and FD. FD patients for whom IB-Stim is indicated have also been shown to experience reduction of nausea symptoms.

Substantial Equivalence:
The subject NeurAxis IB-Stim is substantially equivalent to the predicate device, NeurAxis, Inc. IB-Stim – K241533.

The design, materials, packaging, sterilization, and package label of the subject device are identical to those of the predicate device. The indication for use is being expanded to include functional dyspepsia (FD). Real world evidence including clinical literature support these changes, indicating that they do not raise new questions about device safety and effectiveness.

Performance Testing:
There are no changes to the device design. Therefore, previously conducted testing in DEN180057 remains applicable and no additional performance testing is required.

Clinical Data:
A post-hoc analysis of a study was conducted in 23 subjects who met Rome III criteria for FD. Data from those 23 subjects were extracted from a prospective study that enrolled 115 adolescents with pain-associated DGBIs recruited from a tertiary care pediatric gastroenterology clinic. The treatment arm subjects were treated with IB-Stim and control arm subjects had a sham device. At extended follow-up (8-12 weeks after the end of treatment), 7 of 13 subjects treated with active IB-Stim continued to have at least a 30% reduction in abdominal pain compared to zero of 10 subjects receiving sham treatment, consistent with the results observed in the general study population of adolescents with pain associated DGBIs. Additionally, FD patients reported reduced nausea symptoms when comparing the IB-Stim and sham group at extended follow-up. Given the limitations of a post-hoc analysis in a small subgroup of FD subjects, real world evidence including clinical literature supports these findings.

In addition, no serious adverse events were reported for these patients. Recommendations from the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) based on clinical literature and current practice of medicine support use of PENFS for functional abdominal pain.

Conclusion:
The subject device is determined to be substantially equivalent to the predicate device.