October 16, 2025

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

Re: K252024
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: July 17, 2025
Received: July 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,

SIVAKAMI VENKATACHALAM -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252024

Please provide the device trade name(s).

NeurAxis IB-Stim (01-1020)

Please provide your Indications for Use below.

The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 8 years and older 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary
IB-Stim
June 26, 2025

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

Primary/Secondary Contact: Dawn Norman – Partner
MRC Global
9085 E. Mineral Cir., Suite 110
Centennial, CO 80112
Phone: (618) 604-3064
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Kathy Remsen – Regulatory Consultant
(901) 606-4856
Email: kathy.remsen@askmrcglobal.com

Company Contact: Dr. Thomas J. Carrico, CRO

Trade Name:	NeurAxis IB-Stim (01-1020)
Common Name:	Non-implanted nerve stimulator for pain associated with irritable bowel syndrome (ibs)
Classification:	Class II
Regulation:	21 CFR 876.5340
Regulation Name	Non-implanted nerve stimulator for functional abdominal pain relief
Panel:	Neurology
Product Code:	QHH
Primary Predicate:	NeurAxis IB-Stim (K250451)

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 years and older 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.

Substantial Equivalence:

The subject NeurAxis IB-Stim is substantially equivalent to the predicate device, NeurAxis, Inc. IB-Stim – K250451.

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 for the desired age group (from “8-21 years of age” to “8 years and older”). The extrapolation of clinical data from pediatric to adult indications to support that this change does not raise new questions about safety and effectiveness.

Performance Testing:

There are no changes to the design. Therefore, previously conducted testing remains applicable and no additional performance testing is required.

Clinical Data:

The randomized clinical studies sponsored and conducted by the sponsor in the previous DEN180057, real world evidence including clinical literature support the safety and effectiveness of the device in pediatrics and adolescents. Review of clinical literature and extrapolation of that data to the adult population supports the use of the device in patients 8 years and older.

Conclusion:

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