December 6, 2024

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

Re: K242304
Trade/Device Name: Red
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: KLA, FFX
Dated: November 4, 2024
Received: November 4, 2024

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,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
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.

Submission Number *(if known)*

K242304

Device Name

RED

Indications for Use *(Describe)*

RED is used to evaluate the neuromuscular function of the patient's ability to expel its contents from the rectum and as a qualitative test for rectal hypersensitivity. RED helps identify patients with rectal hypersensitivity who experience desire or urge-to-defecate at lower volumes of distension. RED is intended to be used in a clinical setting by trained health care providers in adult populations.

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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510(k) Summary

RED

August 03, 2024

Company:
NeurAxis, Inc.
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Company Contact:
Dr. Thomas J. Carrico, CRO

Trade Name:
RED

Regulation Name:
Gastrointestinal motility monitoring system

Classification:
Class II

Regulation:
21 CFR 876.1725

Panel:
Gastroenterology/Urology

Product Code:
KLA, FFX

Primary Predicate:
K180135 THD SpA THD Anopress with THD SensyProbe K823701 Mui SR1B Single-Use Anorectal Balloon Expulsion Device

Device Description:
RED has been designed to duplicate test performance of traditional balloon expulsion test (BET) and manual sensation testing devices without needing electronics or software. The RED catheter consists of an open-cell foam ball encased inside of a balloon, coupled to a hollow catheter. The insertion end of the device has a rounded tip for comfortable insertion through the anus.

Once inserted and opened, the catheter normalizes to atmospheric pressure which allows the foam to passively and safely expand to its original size. The volume of air it displaces when inflated in room air is 52ml. This passive expansion provides the same function as filling an empty balloon with water or air. When expanded, the volume of material inside the patient's rectum is perceived by the patient similar to how patients perceive stool, and this may trigger the desire to defecate. This is measured by asking patients the questions on perceived desire to defecate according to the London Classification that define the evaluation of rectal sensation. After the sensation evaluation, while in the seated or left lateral decubitus position, the patient is instructed to attempt to expel the device in a set amount of time. If the patient is unable to expel the device, the practitioner may gently remove the balloon manually.

Indications for Use:
RED is used to evaluate the neuromuscular function of the patient's ability to expel its contents from the rectum and as a qualitative test for rectal hypersensitivity. RED helps identify patients with rectal hypersensitivity who experience desire or urge-to-defecate at lower volumes of distension. RED is intended to be used in a clinical setting by trained health care providers in adult populations.

Substantial Equivalence:
The subject NeurAxis RED device is substantially equivalent to the predicate devices, THD SpA THD Anopress with THD SensyProbe (K180135) and Mui SR1B Single Use Anorectal Balloon Expulsion Device (K823701)

The design, materials, use and labeling of the subject device are similar to that of the predicates, bench and clinical testing has been performed to support the ensure safe and effective use of the device and do not raise new questions about safety and effectiveness.

Differences in volumes administered do not introduce any risk from a diagnostic perspective. As anyone with an urge-to-defecate at RED volumes would be considered hypersensitive under London criteria. The indication also qualifies that the product would only detect hypersensitivity in patients who experience them at lower volumes.

RED offers benefits with respect to assessing hypersensitivity. Firstly, the equipment and complexities required to use the primary predicate greatly limits the access to hypersensitivity testing. As such, the large subpopulation of individuals who are hypersensitive to lower volumes, but are never tested due to testing complexities of the predicate, are likely to benefit greatly through referral to physical therapy. Further, as the sensitivity evaluation simply requires asking a question about urge to defecate for individuals who are already undergoing rectal expulsion testing, it provides that added benefit at no additional risk than rectal expulsion testing alone with RED would provide.

The subject device and predicate devices are all intended to evaluate rectal sensitivity and expulsion. The subject device is similar in technological characteristics to the predicate devices. The minor differences in technological characteristics between the

subject device and predicates do not introduce any different questions of safety or effectiveness.

Performance Testing:
Neuraxis performed a variety of bench testing to demonstrate the safety and performance of the RED device to support suitable inflation, patient evaluation, and removal of the balloon. The tests included:

- Inflation Time and Diameters Testing per ISO 10555-4:2023
- Tensile Force Testing per ISO 10555-1:2023
- Stiffness Testing per ISO 10555-1:2023
- Simulated Removal Testing

Clinical Data:
Clinical evidence from a prospective trial of 60 adults clearly supports product safety and performance and the indications for use in that RED can safely be used to evaluate neuromuscular function of the patient's ability to expel its contents from the rectum in adults with functional constipation (defined by Rome IV criteria). The study also demonstrates that RED can be safely and effectively used as a device for qualitative testing for rectal hypersensitivity, whereas 31.0% of patients experienced rectal hypersensitivity with RED distended when queried on the patient perception to defecate.

Conclusion:
The subject device is determined to be substantially equivalent to the predicate device. The subject device and predicate devices are all intended to evaluate rectal sensitivity and expulsion. The subject device is similar in technological characteristics to the predicate devices. The minor differences in technological characteristics between the subject device and predicates do not introduce any different questions of safety or effectiveness.