January 18, 2024

ZMI Electronics Ltd.
Lawrence Liu
Regulatory Affairs Section Manager
6F-1, 286-4, Shin Ya Road
Kaohsiung, 806
Taiwan

Re: K231166
Trade/Device Name: Levina Incontinence Stimulation Electrodes
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI, HIR
Dated: December 18, 2023
Received: December 18, 2023

Dear Lawrence Liu:

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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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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)*
K231166

Device Name
Levina Incontinence Stimulation Electrodes

Indications for Use *(Describe)*
Levina Incontinence Stimulation Electrodes are intended to provide electromyography feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

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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Section 5: 510(k) Summary

1. **Submitter Information**

Applicant

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Date Summary Prepared: January 17, 2024

2. **General Device Informaion**

Device Name: Levina Incontinence Stimulation Electrodes
Common / usual name: Stimulator, Electrical, Non-implantable, For Incontinence
Model: PFR-XX
Regulation Number: 21 CFR 876.5320
Classification Name: Nonimplanted electrical continence device
Regulatory Class: Class II
Product Code: KPI
Subsequent Product Code: HIR (Obstetrical and Gynecological Diagnostic Devices)

3. **Predicate Device Information**

Primary Predicate

510K Number: K222528
Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA)
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. **Device Description**

Levina Incontinence Stimulation Electrodes are used to treat incontinence when paired with compatible, FDA-cleared electrical stimulators. The probes are intended to provide electrical stimulation to pelvic musculature and for the purpose of rehabilitation of pelvic floor muscles and restoration of neuromuscular control during treatment. The probes come in different models and are available for both vaginal and rectal insertion. The probes are used directly by the patients for home care and are for single-patient, repeat-use. The device comes non-sterile and should be cleaned before and after each use with water and mild soap or neutral detergent.

5. Indication of Use

Levina Incontinence Stimulation Electrodes are intended to provide electromyography feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

6. Comparison to the PredicateDevice

The following features are compared among the predicate devices and our models.

Technological Characteristics	Subject Device	Primary Predicate	Comparison & Impact
Manufacturer	ZMI Electronics Ltd.	Well-Life Healthcare Ltd.	-
Name / Model	Levina Incontinence Stimulation Electrodes PFR-XX	Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA)	-
US FDA Listed	K231166	K222528	-
Product Code	KPI & HIR	KPI & HIR	Identical
Regulation Number	876.5320	876.5320	Identical
Regulation Name	Nonimplanted electrical continence device	Nonimplanted electrical continence device	Identical
Regulatory Class	Class II	Class II	Identical
Indication for Use	to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.	to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of week pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.	Identical
Prescriptive or Over-The-Counter Use	Prescription and OTC Use	Prescription and OTC Use	Identical
Electrode Placement	Vaginal or Rectal	Vaginal or Rectal	Identical
Environment of Used	Home	Home	Identical
Target Population	Patients with incontinence or weak pelvic floor muscles	Patients with incontinence or weak pelvic floor muscles	Identical
Standards	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-18 ISO 10993-17 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	Identical
Materials	Medical Grade PC, Stainless Steel	ABS, Stainless Steel	Similar; Levina probes are made of materials suitable for high temperature disinfection.
Contact Duration	Intermittent mucosal contact < 30 min/session –Stim < 1 hour/session – EMG not exceeding hr combined Stim/EMG	Intermittent mucosal contact < 30 min/session –Stim < 1 hour/session – EMG not exceeding hr combined Stim/EMG	Identical
Electrode Surface Area	Vaginal Probes: 2.8 – 6 cm^2 Anal Probes: 3 – 6.3 cm^2	Vaginal Probes: 4.25 – 7.87 cm^2 Anal Probes: 1.93 – 3.77 cm^2	Different; The range of electrode surface area are within the normal range for other

			cleared devices of this device type
Probe Length	Vaginal Probes: 8 – 10 cm Anal Probes: 7 – 12.5 cm	Not publicly available	Different; The range of probe lengths are within the normal range for other cleared devices of this device type
Probe Diameter	Vaginal Probes: 3.16 – 3.4 cm Anal Probes: 1.2 – 2.8 cm	Not publicly available	Different; The range of probe diameters are within the normal range for other cleared devices of this device type
Usage Conditions	Reusable-Single Patient	Reusable-Single Patient	Identical
Sterility	Not sterilized	Not sterilized	Identical
Reprocessing-Cleaning	Cleaning: washed with soap or neutral detergent (at or near pH7.0) and water after each use and dried thoroughly.	Cleaning: washed with soap and water after each use and dried thoroughly.	Similar

The differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Non-clinical Testing

A series of safety and performance tests, as follows, were conducted on the subject device in accordance with FDA recognized consensus standards and/or guidance:

1) The biocompatibility evaluation for the Levina Incontinence Stimulation Electrodes was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests:
   - ISO 10993-18 Chemical characterization of medical device
   - ISO 10993-17 Establishment of leachable substances
   - ISO 10993-5 Tests for in vitro cytotoxicity
   - ISO 10993-10 Tests for irritation and skin sensitization
   - ISO 10993-23 Tests for irritation

2) Recommendations and requirements outlined in the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” were followed for reprocessing and cleaning instructions in the labeling.

3) Performance Bench Testing was conducted to verify the performance to specifications of the proposed device and included the following:
   - Subclause 8.5.2.3, Patient Leads of Patient Cables of IEC 60601-1:2005, MOD to comply with 21 CFR 898.
   - Visual Inspection
   - Size Measurement
   - Impedance Testing

4) Performance Bench Testing - Stability Testing was performed to verify the stability to product life of the proposed device and included the following:
   - Probe and Lead Wire Connector Stability with Cycling Test
   - Lead Wire Bending Test
   - Lead Wire Tensile Test
   - Tensile strength of cable connection test per ANSI AAMI EC53:2013/(R)2020 related test methods for lead wire strength of cable connection test.

8. Conclusion

Based upon the information presented above, the Levina Incontinence Stimulation Electrodes have the same intended use and similar technological characteristics as the predicate devices Well-Life Probe Electrode for Stimulation/EMG Probe (Model: SA) (K222528). The differences between the subject devices and the predicate devices do not raise different questions in safety and effectiveness. The performance testing provided supports a determination of substantial equivalence to the predicate device. Therefore, it can be concluded that Levina Incontinence Stimulation Electrodes are substantially equivalent to the predicate device.