March 27, 2025

ZMI Electronics Ltd.
Lawrence Liu
Section Manager
6F-1, 286-4, Shin Ya Road, Chien Chen District
Kaohsiung, 806
TAIWAN

Re: K241862
Trade/Device Name: Levina Pelvic Floor Muscle Stimulator (RS-48)
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: February 25, 2025
Received: February 25, 2025

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.

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,

Angel A. Soler-garcia -S

for
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K241862

Device Name
Levina Pelvic Floor Muscle Stimulator Model: RS-48

Indications for Use *(Describe)*
The device is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

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

## 1. Submitter Information


| | |
|---|---|
| 510 (k) submitter: | ZMI Electronics Ltd. |
| Address: | 6F-1, 286-4, Shin-Ya Road, Kaohsiung, Taiwan 806<br>Phone: +886-7-8150053<br>Fax: +886-7-8150057<br>Email: mail@zmi-electronics.com |
| Applicant Contact Person: | Lawrence Liu<br>Regulatory Affairs Manager<br>Phone: +886-7-8150053 Ext 351<br>Fax: +886-7-8150057<br>E-mail: lawrence@zmi-electronics.com |
| Preparation date: | March 26, 2025 |


## 2. Device Name

| | |
|---|---|
| Trade Name of the Device: | Levina Pelvic Floor Muscle Stimulator Model: RS-48 |
| Common Name: | Nonimplanted electrical continence device |
| Classification Name: | Stimulator, electrical, non-implantable, for incontinence |
| Classification Regulation: | 21 CFR 876.5320 |
| Device Class: | II |
| Panel: | Gastroenterology/Urology |
| Product Code: | KPI |

## 3. Predicate and Reference Devices

| | 510(k)# | Trade Name |
|---|---|---|
| Predicate | K160773 | Yarlap II |
| Reference | K081480 | Kegel8 |
| | K230983 | Unicare (K-UNICARE-USA) |

The predicate and reference devices have not been subject to a design related recall.

## 4. Device Description

Levina Pelvic Floor Muscle Stimulator is a non-implantable, home use device for the treatments of stress, urge, and mixed urine incontinence through the intravaginal probe's electrical stimuli to the muscles of the pelvic floor to induce Kegel-like contractions, which help users to achieve pelvic floor muscle strengthening for maintaining urinary continence in women.

The subject device includes a remote control, a stimulator pod and a vagina stimulation probe. Both the remote control and the stimulator pod are powered by an off-the-shelf 3.7V lithium-ion polymer battery. The remote control has a 1.77" TFT LCD screen and 4 buttons to control the stimulator pod. The stimulator pod has two output channels and will perform electrical stimulation according to the parameter settings sent by the remote control.

The device is supplied with a reusable (single-patient use) vaginal, dual-electrode, stimulation probe.

## 5. Indications For Use

The device is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

## 6. Comparison of the Technological Characteristics with Predicate Device

| Technological/ Performance Characteristics | | Subject Device | Predicate Device |
|---|---|---|---|
| Trade/Device Name | | Levina Pelvic Floor Muscle Stimulator | Yarlap II |
| 510(k) Number | | K241862 | K160773 |
| Indications for Use | | The device is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women | The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women |
| Environments of Use | | Home environment | Home environment |
| Target Population | | women with incontinence or weak pelvic floor muscles | women with incontinence or weak pelvic floor muscles |
| Prescription or Over-the-Counter (OTC) | | Prescription Use & OTC | Prescription Use & OTC |
| Electrode Types | | Incontinence probe | Incontinence probe |
| Waveform | | Biphasic, Symmetrical | Biphasic, Symmetrical |
| Shape | | Rectangular | Rectangular |
| Maximum Output Voltage (volts) | @500Ω | 40 | 40 |
| | @2kΩ | 50 | 50 |
| | @10kΩ | 50 | 95 |
| Maximum Output Current (mA) | @500Ω | 80 | 80 |
| | @2kΩ | 25 | 50 |
| | @10kΩ | 5 | 19 |
| Pulse Width (μsec) | | 200~300 | 200~250 |
| Frequency (Hz) | | 12~50 | 2~100 |

| | | | |
|---|---|---|---|
| For multiphasic waveforms only: | Symmetrical phases | Yes | Yes |
| | Phase Duration (μsec) | 20-150 | 100~125 |
| Maximum Phase Charge (@500Ω) (μC) | | 12 | 10 |
| Electrode Area | | 6cm$^2$ | 6.4cm$^2$ |
| Maximum (peak) Current Density (mA/cm$^2$) | | 13.33 | 12.5 |
| Maximum Current Density (@500Ω) (mA/cm$^2$) rms | | 1.63 | 1.98 |
| Maximum Average Current (average absolute value), (mA) | | 1.2 | 2 |
| Maximum Average Power Density (@500Ω) (mW/cm2) | | 8 | 12.5 |

As evidenced by the above table, both the subject and the predicate devices have the same intended use, but the subject and predicate devices have different technological characteristics. The reference devices were used to support the stimulation parameters of the subject device. Additionally, performance testing was conducted on the subject device to evaluate its safety and effectiveness. Overall, it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

## 7. Non-Clinical Testing

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices* — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance*

- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests*

- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"

- Cybersecurity risk management activities according to FDA Guidance *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issued September 27, 2023*

- Performance testing according to IEC 60601-1-11*, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

- Performance test according to IEC 60601-2-10, *Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

- Electrical performance testing to verify the stimulation parameters

All pre-determined acceptance criteria were met.

## 8. Conclusions

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.