September 8, 2021

Renovia, Inc.
% Jacqueline Schmainda
Director, QA/RA
Bold Type
2100 N. Alafaya Trail
Orlando, FL 32826

Re: K212495
Trade/Device Name: leva Pelvic Health System
Regulation Number: 21 CFR §884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: August 6, 2021
Received: August 9, 2021

Dear Jacqueline Schmainda:

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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)*

K212495

Device Name

leva Pelvic Health System

Indications for Use *(Describe)*

The leva Pelvic Health System is intended for:

1) Strengthening of the pelvic floor muscles;
2) Rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence (including overactive bladder) in women.

This device interacts with the user via smart phone technology.

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."

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92.

1. Submitter

Name and Address: Renovia Inc.
263 Summer Street
Boston, MA 02210

Primary Contact: Jacqueline Schmainda
Regulatory Consultant on behalf of Renovia
Renovia Inc.
263 Summer Street
Boston, MA 02210

Phone: 763-269-2069
Email: jackie@boldtype.com

Date Prepared: September 8, 2021

2. Device Information

Trade Name:	*leva* Pelvic Health System
Model:	leva-02
Common Name:	Perineometer
Product Code:	HIR
Regulatory Class:	Class II
Classification Number:	21 CFR 884.1425
Classification Name:	Perineometer
Review Panel:	Gastroenterology/Urology

3. Predicate Information

510(k) Number	Trade Name	Model	Submitter
K192270	*leva* Pelvic Digital Health System	Leva-02	Renovia Inc.

4. Device Description

The *leva* Pelvic Health System ("*leva* PHS" or "*leva* System") is a prescription intra-vaginal device designed to allow the user (or woman) to rehabilitate and strengthen their pelvic floor muscles (PFM) as well as allow them to monitor their progress during pelvic floor muscle training (PFMT). The *leva* system is designed to wirelessly facilitate PFMT in women and to transmit real-time performance data through a dedicated mobile application that has been downloaded onto the patient's mobile device. The *leva* system is designed to be used vaginally and is intended to be used repeatedly by a single patient.

The *leva PHS* consists of a probe, storage case, associated batteries, and the Renovia Digital Health App (App). Thermoplastic elastomer (TPE) was used as the material overlay for the electronics and six accelerometers are contained within the probe. Additional electronics are contained in the storage case to transmit data wirelessly between the device and the App.

5. Indications for Use

The *leva* Pelvic Health System is intended for:

1) Strengthening of the pelvic floor muscles;
2) Rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence (including overactive bladder) in women.

This device interacts with the user via smart phone technology.

6. Comparison of Technological Characteristics

The following table provides a comparison of the *leva* Pelvic Health System to the predicate device.

Characteristic	Predicate Device	Subject Device
Regulatory Information		
Device Name	*leva* Pelvic Digital Health System	*leva* Pelvic Health System
Manufacturer	Renovia Inc.	Renovia Inc.
Technological Characteristics		
Principle of Operation	Provides indication of relative intensity of pelvic floor muscle contraction using accelerometers	Provides indication of relative intensity of pelvic floor muscle contraction using accelerometers
Muscle Stimulation	No	No
Intended Anatomical Location	Vagina	Vagina
Use Model	Single patient, reusable	Single patient, reusable
Sterility	Clean, non-sterile	Clean, non-sterile
Display Information	Graphical and numeric based on applied bending, anatomical overlay	Graphical and numeric based on applied bending, anatomical overlay
Device Materials	• Probe: Thermoplastic Elastomer (TPE) • Probe Battery Pack: Acrylonitrile Butadiene Styrene (ABS)	• Probe: Thermoplastic Elastomer (TPE) • Probe Battery Pack: Acrylonitrile Butadiene Styrene (ABS)
Patient Contact (Contact Duration)	• Probe: Direct (<24 hours) • Probe Battery Pack: Direct (<24 hours) • Vaginal Probe Hub: Indirect (Incidental) • Battery Pack Cap: Indirect (Incidental)	• Probe: Direct (<24 hours) • Probe Battery Pack: Direct (<24 hours) • Vaginal Probe Hub: Indirect (Incidental) • Battery Pack Cap: Indirect (Incidental)

See Section 7 for discussion of modifications made to the Ieva Pelvic Health System.

7. Summary of Nonclinical Testing and Risk Analysis

The following non-clinical performance testing and risk analysis was performed to support modifications to the leva Pelvic Health System:

A. Biocompatibility

Biocompatibility assessment was done, as needed, based on the changes made to the device. To ensure patient-safety, all the patient-contacting material was subjected to biocompatibility testing in compliance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, for mucosal surface for limited, less than 24 hours duration including:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)

Biocompatibility testing demonstrated that the subject device, leva Pelvic Health System, is as safe and effective, and performs as well as the predicate device, leva Pelvic Digital Health System.

B. The sponsor reported other changes in this special 510 (k) which are stated below:

- **Hardware (H):** Change of the adhesive on the battery case, Printed Circuit Board (PCB)/Printed Circuit Board Assemblies (PCBA), battery vendor change, and product labeling modifications.
- **Embedded software (firmware) (F):** Software changes related to performance improvement, communications, diagnostic and bug fix modifications.
- **Mobile Application Software (RA):** Updates and enhancements for bug fixes and addition/modification of general content (e.g., educational videos added) to provide additional information and clarity to improve the user experience.
- **Manufacturing (M) and Risk Analysis (D):** Manufacturing quality control related changes and updates to the risk analysis modifications.

The following testing was done on the subject device to ensure that the device continues to meet the requirements for substantial equivalence:

- Software and firmware design verification testing
- Manufacturing testing protocol verification

All the changes reported above are minor and did not alter the substantial equivalence of the leva Pelvic Health System.

8. Conclusion

Based on the comparison and analysis above, Renovia has demonstrated that the *leva Pelvic Health System* is substantially equivalent to the predicate device.