April 4, 2018

Renovia Inc.
Gina Prochillo-Cawston
Director, Business Integrity, Compliance and Quality
263 Summer St., 5th Floor
Boston, Massachusetts 02210

Re: K180637
Trade/Device Name: leva Pelvic Digital Health System
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: Class II
Product Code: HIR
Dated: March 9, 2018
Received: March 12, 2018

Dear Gina Prochillo-Cawston:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180637

Device Name
leva Pelvic Digital Health System

Indications for Use *(Describe)*
The leva Pelvic Digital 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 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.

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510(k) Summary
K180637

Submitter's name and address:
Renovia Inc.
263 Summer St.
Boston, MA 02210

Contact person:
Gina Prochillo-Cawston
Director of Business Integrity, Compliance & Quality
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Date summary was prepared: March 26, 2018

Device Information

Trade/Proprietary Name:	leva Pelvic Digital Health System
Common/Usual Name:	Pelvic Floor Muscle Exerciser
Classification Name:	Perineometer
Regulation Number:	21 CFR 884.1425
Device Classification:	Class II
Product Code:	HIR (perineometer)
Review Panel:	Obstetrics/Gynecology

Predicate Device Identification

510(k) Number:	K133990
Device Name:	leva Rehabilitative Positional Device
Manufacturer:	Remendium Labs, LLC (Renovia Inc, is the current holder of the 510(k))

The predicate device has not been subject to a design-related recall.

Device Description

The leva Pelvic Digital Health System (leva PDHS) is specifically designed to facilitate pelvic floor exercise training to strengthen pelvic floor muscles and for the treatment of stress, mixed and mild to moderate urgency urinary incontinence in women. The leva PDHS is intended to be used repeatedly by a single patient. The device is designed to be used vaginally.

The hardware consists of the training device itself and an associated battery powered electronics box. The training device has a biocompatible, colored silicone covering

which isolates the motion electronics from the environment. The leva PDHS uses an app to connect via smart phone. This enables the user to visualize the Kegel exercise she is being trained on.

Indications for Use
The leva Pelvic Digital 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 in women.

This device interacts with the user via smart phone technology.

Predicate Comparison
The following table compares the leva Pelvic Digital Health System to the predicate device with respect to the indications for use and technological characteristics:

Device	**Subject Device** leva Pelvic Digital Health System	**Predicate Device** leva Rehabilitative Positional Device
510(k)Number	K180637	K133990
Manufacturer	Renovia Inc	Remendium Labs, LLC
Common/Usual Name	Perineometer	Perineometer
Regulation Number	884.1425	884.1425
Device Class	Class II	Class II
Product Code	HIR	HIR
Intended Use	The leva Pelvic Digital 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 in women. This device interacts with the user via smart phone technology.	The leva Pelvic Floor Trainer is intended for the purpose of rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild-moderate urge incontinence in women. This device interacts with the user via smart phone technology.
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
Parameter	Relative position of device	Relative position of device
Anatomical Site	Vagina	Vagina
Single Patient Device	Yes	Yes
Reusable	Yes	Yes
Sterile	Non-sterile	Non-sterile
Information Display	Graphical and numeric based on applied bending, anatomical overlay	Graphical and numeric based on applied bending, anatomical overlay
Probe Material	Silicone	Silicone

The leva Pelvic Digital Health System has the same intended use and technological characteristics compared to the predicate device. The are no different questions of safety and effectiveness.

Summary of Non-Clinical Testing

Non-clinical testing provided in the predicate submission (K133990) was leveraged in the current submission as the device technology has not changed since the prior clearance and the only change in this submission was a modification to the indication for use that did not require additional supporting performance data. A summary of the performance testing used to support the current submission is provided below:

A. Hardware Verification Testing: The device was subjected to testing to ensure that the device design conforms to the requirements of the Marketing Specification, Product Specification and System Hazards Analysis. Specific device testing included: measurement and inspection of engineering drawings and specifications, testing of the ability of the cable and vaginal device to withstand pulling for over 1,460 cycles (expected lifetime of the device), cleaning of the device over 1,460 times (expected lifetime of the device), and +/-20° bending of the device for over 1,460 cycles (expected lifetime of the device).

B. Biocompatibility: 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, including cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation (ISO 10993-10).

C. Software: Software validation was performed and completed with no outstanding anomalies. Software documentation was provided in accordance with FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005 for a minor software level of concern.

D. Electrical Safety and Electromagnetic Compatibility: The subject device was tested and found to conform to the requirements of the following:

   i. IEC 60601-1:2005 (3rd Edition), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

   ii. IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

   iii. IEC 60601-1-11 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

E. Packaging Testing: Device packaging was subjected to ISTA 2A-2011 “Partial Simulation Performance Test Procedure for Packaged Products 150 lb (68 kg) or Less” testing, which included: Atmospheric Preconditioning, Atmospheric Conditioning, Compression, Initial Random Vibration, Impacts, Final Random Vibration. The packaging was found to adequately protect the device during shipping and storage.

F. Usability Testing: Usability testing was performed using lay volunteers and comprised: reading the Instructions for Use and Quick Start Guide, setting up the system, using the system correctly, performing a mock Kegel, interpreting the user interface, cleaning, storage, and disposal. All participants successfully completed all tests.

Summary of Clinical Testing
Not Applicable

Conclusion
Based on the comparison and analysis above, the leva Pelvic Digital Health System is substantially equivalent to the predicate device.