November 22, 2019

Renovia Inc.
Gina Prochilo-Cawston
Director of Regulatory
263 Summer St., 5th Floor
Boston, MA 02210

Re: K192270
Trade/Device Name: Leva Pelvic Digital Health System
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: October 28, 2019
Received: October 29, 2019

Dear Gina Prochilo-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. 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); 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,

Ángel A. Soler-García, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192270

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 (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.

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510(k) Summary

A 510(k) Summary was prepared in accordance with 21 CFR 807.92 and is provided on this page.

Submitter

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

Primary Contact: Gina Prochilo-Cawston
Director of Regulatory
Renovia Inc.
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Boston, MA 02210
Phone: (857) 324-3089
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Date Prepared: November 18, 2019

Device Information

Device Trade Name:	*leva* Pelvic Digital Health System
Device Model #:	*leva*-02
Common Name:	Pelvic Muscle Exerciser
Classification Name:	Perineometer
Product Code:	HIR
Classification Number:	884.1425
Regulatory Class:	Class II
Review Panel:	GU - Gastroenterology/Urology
Medical Specialty:	OB - Obstetrics/Gynecology

Predicate Device Information

510(k) Number:	K180637
Device Trade Name:	Leva Pelvic Digital Health System
Device Model #:	*leva*-01
Common Name:	Pelvic Muscle Exerciser
Classification Name:	Perineometer
Product Code:	HIR
Classification Number:	884.1425
Regulatory Class:	Class II
Review Panel:	GU - Gastroenterology/Urology
Medical Specialty:	OB - Obstetrics/Gynecology
Manufacturer:	Renovia Inc.

I. Device Description

The *leva-02 PDHS* 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-02* is designed to wirelessly facilitate pelvic floor muscle training (PFMT) in women and to transmit real-time performance data through a dedicated mobile application that has been downloaded to the patient's mobile device. The *leva*-02 is designed to be used vaginally and is intended to be used repeatedly by a single patient.

The *leva*-02 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.

II. 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.

III. Comparison of Technological Characteristics

The following table compares the *leva* Pelvic Digital Health System (*leva-02*) to the predicate device (*leva-01*) with respect to the indications for use and primary technological characteristics:

Element	Subject Device *leva* Pelvic Digital Health System ***Model: leva-02***	Predicate Device *leva* Pelvic Digital Health System ***Model: leva-01***
510(k)Number	This submission	K180637
Manufacturer	Renovia Inc.	Renovia Inc.
Common/Usual Name	Perineometer	Perineometer
Classification 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 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.
Principle of Operation	Provides indication of relative intensity of pelvic floor muscle contraction using accelerometers	Provides indication of relative movement of pelvic floor muscle contraction using accelerometers
Muscle Stimulation	No	No
Intended Anatomical Location	Vagina	Vagina
Single Patient Device	Yes	Yes
Reusable	Yes	Yes
Sterile	Clean, Non-sterile	Clean, Non-sterile
Information Display	Graphical and numeric based on applied bending, anatomical overlay	Graphical and numeric based on applied bending, anatomical overlay
Device Materials	Thermoplastic Elastomer (TPE- probe	Silicone

Element	Subject Device *leva* Pelvic Digital Health System *Model: leva-02*	Predicate Device *leva* Pelvic Digital Health System *Model: leva-01*
Direct Contact	covering material) Acrylonitrile Butadiene Styrene (ABS-probe battery pack)	

IV. Summary of Non-Clinical Testing and Risk Analysis

The following non-clinical performance testing and risk analysis was performed to support the *leva-02* PDHS:

A. Hardware

Hardware verification was performed in accordance with predefined test procedures and acceptance criteria and included the following assessments:

- Dimensional analysis
- Accelerometer performance
- Device integrity (e.g., pull force, bend, material) under repeated motion
- Wireless communications
- Component connections (i.e., probe, battery pack)
- Cleanability

Hardware verification demonstrated that the subject device, *leva*-02, is as safe, as effective, and performs as well as the predicate device, *leva*-01.

B. Software

Software validation was performed in accordance with IEC 62304 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" (2005) for a minor software level of concern. The *leva-02* PDHS was tested and found to conform to the requirements of the following standards:

- IEC 62304:2006 (First Edition) + A1:2015, Medical device software – Software life cycle processes

Software verification demonstrated that the subject device, *leva*-02, is as safe, as effective, and performs as well as the predicate device, *leva*-01.

C. Usability

Usability and Human Factors testing was performed using layperson volunteers. Testing included:

- Reading Instructions for Use and Quick Start Guide
- Setting up the system
- Using system correctly
- Cleaning, storage, disposal

All participants successfully completed all testing. Usability testing demonstrated that the subject device, *leva*-02, is as safe, as effective, and performs as well as the predicate device, *leva*-01.

D. 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, for mucosal surface for 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*-02, is as safe, as effective, and performs as well as the predicate device, *leva*-01.

E. Electrical Safety and Electromagnetic Compatibility

The *leva-02* PDHS was tested and found to conform to the requirements of the following standards:

- IEC 60601-1:2005 + A1: 2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-6:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 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
- IEC 60601-1-2 ed 4.0 (2014-02), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 61000, Electromagnetic Compatibility

Electrical Safety and Electromagnetic Compatibility testing demonstrated that the subject device, *leva*-02, is as safe, as effective, and performs as well as the predicate device, *leva*-01.

F. Additional Testing

The *leva-02* PDHS was found to conform to the following additional standards and requirements:

- IEC 62366-1:2015, Medical Devices -- Part 1: Application of Usability Engineering to Medical Devices
- CISPR 11:2015+A1:2016+A2:2019, Industrial, scientific and medical equipment — Radio-frequency disturbance characteristics - Limits and methods of measurement
- 47CFR15.247 Subpart C: 02/2019, Federal Communications Commission, Radio Frequency Devices, Intentional Radiators
- 47CFR15.247 Subpart B: 02/2019, Federal Communications Commission, Radio Frequency Devices, Unintentional Radiators
- RSS-247 Issue 2 February 2017, Canada Radio Equipment Standards, Radio Standards Specifications, Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and License-Exempt Local Area Network (LE-LAN) Devices
- ICES-003 Issue 6 Published: January 2016, updated April 2017, Canada Interference Causing Equipment Standards, Information Technology Equipment (Including Digital Apparatus) — Limits and Methods of Measurement
- RSS-Gen Issue 5 April 2018, Canada Radio Equipment Standards, Radio Standards Specifications, General Requirements for Compliance of Radio Apparatus
- RSS-102 Issue 5 March 2015, Canada Radio Equipment Standards, Radio Standards Specifications, Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)
- CISPR 25 Ed 3:2008. Vehicles, boats and internal combustion engines. Radio disturbance characteristics - limits and methods of measurement for the protection for on-board receivers.
- EN 50121-3-2:2015. Railway Applications - Electromagnetic Capability.
- RTCA DO-160G; Section 21.4 RF Radiated Emission; Published: December 8, 2010. Environmental Conditions and Test Procedures for Airborne Equipment.

The additional testing demonstrated that the subject device, *leva*-02, is as safe and as effective and performs as well as the predicate device, *leva*-01.

G. Packaging

The *leva-02 PDHS* packaging system will be subjected to ISTA 2A-2011 "Partial Simulation Performance Test Procedure for Packaged Products 150 lb. (68 kg) or Less" testing, prior to commercial launch. To ensure the packaging adequately protects the device during shipping and storage this testing will include:

- Atmospheric Preconditioning
- Compression
- Initial Random Vibration

- Impact
- Final Random Vibration

H. Risk Analysis

In addition to non-clinical performance testing, a risk analysis was performed in accordance with ISO 14971:2012 to identify potential hazards and hazardous situations, estimate and evaluate the potential risks, and implement risk control measures to mitigate the potential risks of the device, where possible.

The risk analysis demonstrated that the subject device, *leva*-02, is as safe, as effective, and performs as well as the predicate device, *leva*-01.

V. Clinical Testing

Clinical testing was not required to support a substantial equivalence determination for the *leva-02 PDHS*.

VI. Conclusion

Based on the comparison and analysis above, Renovia has demonstrated that the *leva-02 PDHS* is substantially equivalent to the predicate device.