June 30, 2022

Renovia Inc.
% Jacqueline Schmainda
Regulatory Consultant
Bold Type
2100 N Alafaya Trail
Orlando, FL 32826

Re: K213913
Trade/Device Name: leva Pelvic Health System
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: Class II
Product Code: HIR
Dated: June 1, 2022
Received: June 2, 2022

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); 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,

for
Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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)*
K213913

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;
3) Rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence (>3-month uncontrolled passage of feces) 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.

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510(k) Summary

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:	June 27, 2022

2. Device Information

Trade Name:	*leva*® Pelvic Health System
Model:	leva-02
Common Name:	Perineometer
Product Code:	HIR
Regulatory Class	Class II
Regulation Number:	21 CFR 884.1425
FDA Panel:	Obstetrics / Gynecology

3. Predicate Information

510(k) Number	Trade Name	Applicant
K212495	*leva* Pelvic Health System	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 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.

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;
3) Rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence (≥3-month uncontrolled passage of feces) 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	***Subject Device*** ** *leva* PHS This Submission**	***Predicate Device*** ** *leva* PHS K212495**
Regulatory Information		
Brand Name	*leva* Pelvic Health System	*leva* Pelvic Health System
Manufacturer	Renovia Inc.	Renovia Inc.
Model Number	*leva*-02	*leva*-02
Common or Usual Name	Perineometer	Perineometer
Regulation	21 CFR 884.1425	21 CFR 884.1425
Class	Class II	Class II
Product Code	HIR	HIR
Intended Use / Indications for Use		
Intended Use	Strengthen pelvic floor muscles for the treatment of urinary incontinence and fecal incontinence	Strengthen pelvic floor muscles for the treatment of urinary incontinence
Indications for Use Statement	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; 3) Rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence (≥3-month uncontrolled passage of feces) in women. This device interacts with the user via smart phone technology.	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.

510(k) Summary

RenoVia

Characteristic	*Subject Device* ***leva* PHS** **This Submission**	*Predicate Device* ***leva* PHS** **K212495**
Technological Characteristics		
Principle of Operation	Provides indication of relative position of pelvic floor muscle contraction using accelerometers	Provides indication of relative position of pelvic floor muscle contraction using accelerometers
Mechanism of Action	Lift and Squeeze for pelvic floor muscle strengthening. The *leva* sensor hardware (probe) transmits biofeedback to *leva* App which is displayed to user.	Lift and Squeeze for pelvic floor muscle strengthening. The *leva* sensor hardware (probe) transmits biofeedback to *leva* App which is displayed to user.
Electrical Stimulation	No	No
Parameter	Relative position of device	Relative position of device
Anatomical Use	Vaginal only	Vaginal only
Single Patient Device	Yes	Yes
Reusable	Yes	Yes
Sterility	Non-sterile, clean	Non-sterile, clean
Information Display	Graphical and numeric based on implied bending, anatomical overlay	Graphical and numeric based on implied bending, anatomical overlay
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)
Patient Contact Materials	• Probe: Thermoplastic Elastomer • Probe Hub: Polypropylene • Battery Pack: Hard Plastic	• Probe: Thermoplastic Elastomer • Probe Hub: Polypropylene • Battery Pack: Hard Plastic
Probe Shape	• Oval	• Oval
Storage	• Storage case provided with device	• Storage case provided with device
Primary System Elements	• Wireless Vaginal Probe • User Interface Device (i.e., smartphone, tablet) • Mobile Application	• Wireless Vaginal Probe • User Interface Device (i.e., smartphone, tablet) • Mobile Application
Power Source	• **Device:** Non-rechargeable silver oxide 1.5V Coin Cell • **Storage Case:** Non-rechargeable CR2032 3V Coin Cell	• **Device:** Non-rechargeable silver oxide 1.5V Coin Cell • **Storage Case:** Non-rechargeable CR2032 3V Coin Cell
Wireless Technology	• Bluetooth Low Energy (BLE)	• Bluetooth Low Energy (BLE)

7. Summary of Nonclinical Testing and Risk Analysis

Nonclinical testing of the *leva* Pelvic Health System was not required for the expansion of the indications for use statement. Minor modifications made to the device since last clearance were summarized in this submission and included reference to design verification and/or design validation activities and risk analyses, where applicable.

A. Hardware Changes

There were no hardware changes made to the *leva* Pelvic Health System to support the expanded indications for use statement.

B. Software Changes

No software changes were made to the medical device functionality of the *leva* Pelvic Health System. More specifically, there were no changes to the mobile application which modified how the user interacts with the device. All software modifications were reviewed and evaluated following the software life cycle processes for medical device software as defined by IEC 62304. The only changes to the software of the *leva* Pelvic Health System relate to non-medical device functionality (aka "other functionality") under FDA's guidance on "*Multiple Function Device Products: Policy and Considerations*" (2020). Software modifications related to "other functionality" included the addition of educational information regarding fecal incontinence to the mobile application. Regression analyses were conducted to determine the scope of software testing to be re-executed related to these modifications and the test results supported the implementation of updated software version.

8. Clinical Testing

The mechanism of action of the *leva* Pelvic Health System has been the subject of multiple published, peer-reviewed clinical trials studying its efficacy, including the two studies outlined below. The data from the referenced clinical studies supports the *leva* Pelvic Health System can serve as a safe and effective aid to provide feedback when performing pelvic floor training in the treatment of fecal incontinence. In all studies, the *leva* device was used vaginally to perform the same type of pelvic floor muscle training.

A. REN-17 Study (NCT04027335):

The REN-17 Study was a ten (10) week, single-arm, open-label study involving thirty-one (31) participants who engaged in pelvic floor muscle training (PFMT) using the *leva* Pelvic Health System (*leva*-01). Subject selection was based on meeting pre-defined screening criteria, including fecal incontinence ("**FI**") defined as any uncontrolled loss of liquid or solid fecal material that occurs at least monthly over the last three (3) months and is bothersome enough to desire treatment.

REN-17 – Summary	
Level of Evidence:	Single-arm study with Performance Goals
Location of Study:	United States only
Primary Effectiveness Endpoint:	Change in St. Mark's Score
Was the study primary endpoint met?	Yes, participants reported a mean St. Mark's Score of 14.6 at baseline which improved to 11.6 at ten weeks (p=0.0047). The sample size needed to avoid a type β error was met.
Adverse events and complications:	There were three adverse events reported as possibly device related – two urinary tract infections and one yeast infection. None of these adverse events were considered serious and the participants continued to participate in the study through the ten-week endpoint.

REN-17 - Patient Accountability	
Stage	**Treatment Group (Single-Arm)**
Enrollment	31 participants
Treatment	27 participants
Primary Effectiveness Endpoint Analysis	26 participants
Primary Safety Endpoint Analysis	27 participants

REN-17 – Study Results				
Endpoint	**n**	**Baseline**	**Week 10**	**Wilcoxon signed rank test**
St. Mark's Score (Vaizey)	26	14.6 ±4.37	11.6 ±5.12	**0.008**
FIQoL - Lifestyle	26	2.7 ±0.85	3.1 ±0.84	**<0.001**
FIQoL - Coping	26	2.2 ±0.73	2.5 ±0.81	**<0.001**
FIQoL - Depression	26	3.0 ±0.68	3.2 ±0.70	**<0.001**
FIQoL - Embarrassment	26	2.1 ±0.84	2.3 ±0.88	0.06
Bowel Diary	21	8.4 ±8.73	4.8 ±3.79	0.052

*Bold text identifies statistical significance <0.05.

B. REN-19 (NCT04508153):

The REN-19 Study was an eight (8) week, randomized controlled trial ("**RCT**") that included two hundred ninety-nine (299) women with stress and stress-dominant mixed urinary incontinence ("**UI**") that included completion of pelvic floor muscle training ("**PFMT**") for all participants (control and treatment groups) and evaluated the participants as follows:

- *Control Group*: Performed PFMT after receiving a standardized written and verbal instructions but without the aid of any device, effectively performing what are commonly called Kegel exercises.
- *Treatment Group*: Performed PFMT using the *leva* Pelvic Health System (*leva*-02).

While the primary endpoints of the Ren-19 RCT involved PFMT for the treatment of stress UI and stress-dominant mixed UI, the trial also included several secondary endpoints including the Colorectal-Anal Distress Inventory, Short Form (the "**CRADI-8**"). The CRADI-8 is a validated patient-reported symptom scale, validated, in part, based on the outcomes of bowel diaries.

Renovia completed a subset analysis of participants from the Ren-19 RCT who indicated they had fecal incontinence ("**FI**") symptoms. Participants included in the subset analysis met all of the inclusion criteria for the larger study and, in addition, indicated they "usually lose stool beyond their control" for well-formed or loose stool, with a bother of at least "somewhat" in their responses to the CRADI-8. Based on the same modified intent to treat plan executed for the larger study, a subset of 92 participants was identified as meeting this additional inclusion criteria.

The purpose of the subset analysis was to evaluate symptom improvement of the 92 participants with FI over the study period within their assigned treatment group and to compare the results between the 48 participants in the control group (*at-home PFMT without leva-02*) and the 44 participants in the intervention group (*at-home PFMT with leva-02*). By focusing on participants with FI, it is possible to better assess the impact of the control treatment vs. the intervention treatment on FI symptoms.

REN-19 Subset Analysis – Summary	
Level of Evidence:	Randomized, multi-arm, unblinded study with an active control
Location of Study:	United States only
Effectiveness Endpoints:	1) Change in participants' symptoms using the Colorectal-Anal Distress Inventory, Short Form (the "**CRADI-8**") 2) Change in participants' condition-specific quality of life assessment using the Colorectal-Anal Impact Questionnaire Short Form (the "**CRAIQ-7**")

REN-19 Subset Analysis - Patient Accountability		
Stage	**Treatment Group (*leva*-02)**	**Control Group (Active)**
Treatment	44 participants	48 participants
Primary Effectiveness Endpoint Analysis	44 participants	48 participants
Primary Safety Endpoint Analysis	44 participants	48 participants

Safety:

There were no treatment-related severe adverse events in either arm of the Ren-19 Study. Looking at only those 92 participants within the FI subset analysis, there were two (2) urinary tract infections in the control (Kegel) group, neither of which were deemed to be intervention related, and none in the intervention (*leva*-02) group. There was one (1) adverse event, vaginal spotting, in one subject which was reported as "possibly" intervention related occurring in the intervention (*leva*-02) arm. This resolved before the end of the study and the participant resumed use of the device without complication through the study endpoint at 8 weeks.

Endpoints:

The Ren-19 subset analysis compared participants' overall CRADI-8 scores and the two individual questions within the CRADI-8 specifically addressing FI, and participants' condition-specific quality of life assessment using the Colorectal-Anal Impact Questionnaire Short Form (the "**CRAIQ-7**") – each at baseline, 8-weeks, and 6-months.

The results of the FI subset analysis demonstrate that FI symptom improvement of those in the *leva*-02 arm was statistically superior to that of participants in the Kegel arm, as summarized in the Results table below.

CRADI-8 Results:

On the CRADI-8, both the Kegel arm and the *leva*-02 arm demonstrated statistically significant improvement that met the minimum clinical important difference ("**MCID**") (-4.68) for the CRADI-8 at 8 weeks. Jelovsek, Chen et. al. found in their 2014 publication, *Minimum Important Differences for Scales Assessing Symptom Severity and Quality of Life in Patients with Fecal Incontinence* (available at doi: 10.1097/SPV.0000000000000078), that the MCID for the CRADI-8 is a reduction of 4.68.

While the improvement in the *leva*-02 arm was greater, there was not a statistically significant difference between the groups at 8 weeks (P=.54). However, the CRADI-8 symptom improvement of the *leva*-02 group was statistically significantly greater at 6 months. This difference at 6 months was driven by the fact that the CRADI-8 results of participants in the Kegel arm did not continue to improve between 8 weeks and 6 months. In the *leva*-02 arm, however, the CRADI-8 results continued to improve between 8 weeks and 6 months.

This result of stronger continued improvement in FI symptoms through 6 months within the *leva*-02 arm is also evident in the results of the questions 3 and 4 of CRADI-8, which are the two questions within the survey that specifically address loss of stool.[1] As shown in Table 4 below, the symptom improvement specific to the control of loose stool was statistically superior within the *leva*-02 arm at 6 months.

CRAIQ-7 Results:

In the CRAIQ-7 assessing participants' condition-specific quality of life, both the Kegel arm and the *leva*-02 arm demonstrated statistically significant improvement at 8 weeks. However, only participants in the *leva*-02 arm reported results that met the MCID (-8.01) for the CRAIQ-7 at 8 weeks (*see Jelovsek, Chen et. al. for MCID on CRAIQ-7*).

While the CRAIQ-7 improvement in the *leva*-02 arm was greater, there was not a statistically significant difference between the groups at 8 weeks (P=.39). However, the CRAIQ-7 improvement of the *leva*-02 group demonstrated improvement that was statistically significantly greater at 6 months (p=0.02). This difference at 6 months was driven by the fact that the CRAIQ-7 results of participants in the Kegel arm did not continue

[1] Question 3 of the CRADI-8 asks: *Do you usually lose stool beyond your control if your stool is well formed?* Question 4 of the CRADI-8 asks: *Do you usually lose stool beyond your control if your stool is loose?*

to improve between 8 weeks and 6 months. In the *leva*-02 arm, however, the CRAIQ-7 results continued to improve between 8 weeks and 6 months.

REN-19 Subset Analysis – Results										
	Baseline to 8 weeks					Baseline to 6 months				
	Baseline	8 Weeks	Abs Mean Difference	Paired t-test	Students t-test	Baseline	6 Months	Abs Mean Difference	Paired t-test	Students t-test
CRADI-8 (full survey)										
Kegel arm	40.9 (±19.9)	29.2 (±22.4)	-5.3 (±14.3)	**<0.001**	0.54	40.9 (±19.9)	29.6 (±20.2)	-6.8 (±15.0)	**<0.001**	**0.01**
***leva*-02 arm**	37.7 (±20.7)	27.8 (±20.6)	-3.0 (±15.0)	**<0.001**		37.7 (±20.7)	17.2 (±19.4)	-8.6 (±13.8)	**<0.001**	
CRADI-8: Question 3 (Loss of Well-Formed Stool)										
Kegel arm	0.9 (±1.6)	0.7 (±1.4)	-0.1 (±1.0)	0.3523	0.53	0.9 (±1.6)	0.5 (±1.3)	-0.1 (±1.1)	0.1914	0.64
***leva*-02 arm**	0.6 (±1.3)	0.5 (±1.3)	0.1 (±0.7)	0.7656		0.6 (±1.3)	0.2 (±0.8)	-0.1 (±0.7)	0.6211	
CRADI-8: Question 4 (Loss of Loose Stool)										
Kegel arm	3.2 (±1.0)	2.0 (±1.7)	-0.2 (±1.4)	**<0.001**	0.45	3.2 (±1.0)	2.0 (±1.9)	-0.2 (±1.4)	**<0.001**	**0.04**
***leva*-02 arm**	3.09 (±1.1)	1.6 (±1.6)	0.2 (±1.5)	**<0.001**		3.09 (±1.1)	1.0 (±1.6)	-0.4 (±1.5)	**<0.001**	
CRAIQ-7										
Kegel arm	23.5 (±27.4)	16.7 (±21.7)	-4.3 (±14.6)	**0.02**	0.39	23.5 (±27.4)	17.5 (±24.7)	-3.8 (±13.1)	0.1175	**0.02**
***leva*-02 arm**	23.5 (±25.0)	12.3 (±17.0)	-5.0 (±13.7)	**<0.001**		23.5 (±25.0)	10.4 (±18.3)	-4.2 (±15.5)	**<0.001**	

*Bold text identifies statistical significance <0.05.

9. Risk Review

In support of the expanded indications for use statement, a risk review was conducted for the use of the *leva* Pelvic Health System as a first-line treatment of chronic fecal incontinence in women. The risk review confirmed that there were no new or increased risks associated with the device which would raise new questions of safety or effectiveness.

10. Conclusion

Renovia has demonstrated that the *leva* Pelvic Health System is as safe and effective as the predicate device for its intended use and substantially equivalent to the predicate device.