July 10, 2020

Pelvital USA, Inc.
% Carrie Hetrick, DDS, MSRS
Principal and CEO
Hetrick Medical Device Consulting, LLC
19123 West 60th Lane
Golden, CO 80403

Re: K200409
Trade/Device Name: Pelvital System
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: May 30, 2020
Received: June 2, 2020

Dear Carrie Hetrick:

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,

Purva Pandya
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200409

Device Name
Pelvital System

Indications for Use *(Describe)*
The Pelvital System is intended for the strengthening of the pelvic floor muscles, which has been found to help women with stress urinary incontinence.

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

Pelvital System

K200409

1. Submission Sponsor

Pelvital USA, Inc.

1000 LaSalle Avenue

SCH 435

Minneapolis, MN 55403

Phone: (612)-804-1319

Contact: Dale Wahlstrom

Title: Chief Executive Officer

2. Submission Correspondent

Hetrick Medical Device Consulting, LLC

19123 West 60th Lane

Golden, CO 80403

Cell Phone: (720) 838-413

Contact: Carrie Hetrick, DDS, MSRS, Principal and CEO

Email: carrie.hetrick@gmail.com

3. Date Prepared

July 9th, 2020

4. Device Identification

Trade/Proprietary Name:	Pelvital System
Common/Usual Name:	Perineometer
Classification Name:	Perineometer
Regulation Number:	21 CFR § 884.1425

Product Code: HIR

Device Class: Class II

Classification Panel: Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

K162689, Bioinfinity (M) Sdn. Bhd., Vibrance Pelvic Trainer

6. Device Description

The Pelvital System is a repeat use, a non-sterile vaginal device intended to condition and strengthen the pelvic floor muscle (PFM) system. The model MTI-1 is designed for in-home use to enhance PFM training during normal Kegel exercises. The product consists of a probe that is inserted into the vagina and a handheld control unit that provides a biofeedback function to inform the user when the correct muscles are being contracted during a Kegel exercise. The probe is designed to provide a resistive surface against which the user can contract the PFM, and an electric motor containing an eccentric weight that causes the probe to oscillate . The probe and the control unit are connected by a cable.

Control Unit: The control unit consists of a 3.7V Lithium-ion Polymer rechargeable battery with a capacity of 680-710 mAh and built-in safety protection. The unit also contains a PCB assembly used to control the motor speed and frequency and to provide the user with the biofeedback information. The control unit housing is made of ABS plastic (Acrylonitrile-butadiene-styrene copolymer).

Probe Unit: The probe unit contains an accelerometer and gyroscope which generate the biofeedback information. It also houses the motor and weight used to generate oscillations. The maximum diameter is 36 mm, and the maximum length is 100 mm. The design includes a winged flange that limits the maximum insertion length to 88 mm. The probe housing is cylindrical and is made of ABS plastic. The probe is the only part of the device that directly contacts the user's vaginal cavity (mucosal membrane contact, ≤24hr) and is covered entirely with a biocompatible medical-grade silicone sheath.

7. Indication for Use Statement

The Pelvital System is intended for the strengthening of the pelvic floor muscles, which has been found to help women with stress urinary incontinence.

8. Substantial Equivalence Discussion

The following table compares the Pelvital System to the predicate device concerning indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	Pelvital USA, Inc.	Bioinfinity (M) Sdn. Bhd.	Significant Differences
Trade Name	**Pelvital System**	**Vibrance Pelvic Trainer**	
510(k) Number	K200409	K162689	Not applicable
Product Code	HIR	HIR	Identical
Regulation Number	21 CFR § 884.1425	21 CFR § 884.1425	Identical
Regulation Name	Perineometer	Perineometer	Identical
Indications for Use	The Pelvital System is intended for the strengthening of the pelvic floor muscles, which has been found to help women with urinary stress incontinence.	The Vibrance Pelvic Trainer (VPT) is intended for the strengthening of the pelvic floor muscles, which has been found to help women with urinary incontinence	Same
Over the Counter (OTC)	Yes	Yes	Identical
Prescription Use	Yes	No	Differs
Anatomical Sites	Vagina	Vagina	Identical
Feature	Resistive vaginal exerciser	Resistive vaginal exerciser	Identical
Target Population	Women with urinary incontinence	Women with mild incontinence	Identical
Anatomical Site	Vagina	Vagina	Identical
Single Patient Device	Yes	Yes	Identical
Single Use or Reusable	Reusable	Reusable	Identical
Provided Sterile	Clean, but not sterile	Clean, but not sterile	Identical
Biofeedback display information	Yes	No	Differs. The subject device displays mechanical transduction information to the user, while the predicate device requires the user to switch out resistance sheaths.
Device Design	A handheld biofeedback device and a vaginally	A handheld device consisting of the Main Body and three gradual	Differs. The main difference between these two devices is

Manufacturer	Pelvital USA, Inc.	Bioinfinity (M) Sdn. Bhd.	Significant Differences
Trade Name	**Pelvital System**	**Vibrance Pelvic Trainer**	
	inserted probe	Resistance Sheaths	the subject device has a handheld Display and Control Unit and does not have resistance sheaths. Performance testing of the subject device does not raise any additional questions for safety or efficacy as performance testing supports safe use of the device.
Material	Main Body: ABS Plastic, PCB Assembly, rechargeable lithium polymer battery (680-710 mAh, 3.7 V) with USB charger Probe: Medical grade silicone (polysiloxane) probe cover, ABS Plastic, PCB Assembly	Main Body: ABS Plastic, PCB Assembly, rechargeable lithium polymer battery (140 mAh, 3.7 V) with USB charger Sheaths: Medical grade silicone (polydimethylsiloxane)	The main difference between these two devices is the replacement of the two low electrical energy coin cell batteries with a rechargeable battery with USB charger.
RoHS Compliant	Yes	Yes	Identical
Operating Principle	Resistive pelvic floor strengthener	Resistive pelvic floor strengthener	Identical
Resistance Component	The Pelvital System (MTI-1) Static resistive component via the vaginally inserted probe.	The Pelvital System (VPT) Electromechanical spring contact offers 3 levels of resistance sheaths with increasing stiffness	Identical
Biocompatibility	Guidelines set forth in ISO 10993 testing results indicate the material is biocompatible, nontoxic, and well tolerated by mucosal membranes.	Guidelines set forth in ISO 10993 testing results indicate the material is biocompatible, nontoxic, and well tolerated by mucosal membranes.	Similar
Chemical Safety	Addressed by	Addressed by	Similar

Manufacturer	Pelvital USA, Inc.	Bioinfinity (M) Sdn. Bhd.	Significant Differences
Trade Name	**Pelvital System**	**Vibrance Pelvic Trainer**	
	biocompatibility testing per ISO 10993	biocompatibility testing per ISO 10993	
Instructions for Use	Manual	Manual	Similar
Energy Use and/or Delivered	Energy is supplied by a rechargeable lithium-polymer battery (680-710mAh, 3.7 V) with USB charging capability	Energy is supplied by a rechargeable lithium-polymer battery (140mAh, 3.7 V) with USB charging capability	Similar
Packaging	The device is sealed plastic bag and manual in a cardboard box	The device is sealed plastic bag and manual in a cardboard box	Identical
Product Dimensions	10.0 cm x 3.6 cm	6 cm x 2 cm	Similar

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Pelvital System and in showing substantial equivalence to the predicate devices that are subject to this 510(k) Submission, Pelvital USA, Inc. completed several tests. The Pelvital System meets all the requirements for the overall design, biocompatibility, and electrical safety testing, and performance confirm that the output meets the design inputs and specifications. The Pelvital System passed all testing stated above, as shown by the acceptable results obtained.

Testing demonstrated the Pelvital System meets all relevant standards requirements. Internal verification and validation testing confirm that the product specifications are met, which are equivalent in design and technological characteristics to the predicate device. The testing results support that the disinfection, electrical safety testing, and functional testing of the device all met or exceeded the standards for the acceptance of the device. Testing of the Pelvital System supports the claims of substantial equivalence to the predicate device. Evaluation of the performance characteristics establishes that the performance, functionality, and reliability of the Pelvital System are substantially equivalent to the predicate device.

The following testing has been performed to support substantial equivalence:

Biocompatibility - The biological safety of the Pelvital System was evaluated in accordance with ISO 10993-1:2009 and guidance document entitled *Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process"* dated June 16th, 2016. Under these, for the stated indications for use, each component of the device's biological safety was evaluated for in vitro cytotoxicity, skin sensitization, and vaginal irritation.

- In Vitro Cytotoxicity test was performed according to ISO 10993-12 and ISO 10993- 5, with the results suggesting that the test articles did not induce a cytotoxic effect.
- Skin Sensitization (Maximization Test) was performed according to ISO 10993-10, with the results suggesting that the device extracts did not produce skin sensitization in guinea pigs.

- Irritation (Vaginal Irritation Study) was performed on New Zealand White Rabbits according to ISO 10993-10, with the results showing that there were no significant clinical signs and gross findings in either the control or test group, and there were no mortalities.

Electromagnetic Compatibility and Electrical Safety - The Pelvital System complies with the applicable voluntary standards, which include ES60601-1, IEC 60601-1-2, and IEC 60601-1-11. The Pelvital System complies with these voluntary standards, including IEC 60601-1 and IEC 60601-1-11 for Electrical Safety and systems used in the home healthcare environment.

Software - All documentation was prepared and submitted for the device per FDA guidance documents. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The device hazard analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and the interaction of processes. The Pelvital System device passed all testing and supported the claim of substantial equivalence and safe operation.

Disinfection/Cleaning: The Pelvital System device is intended for single-patient use. Disinfection studies showed that Dispatch® Hospital Cleaner Disinfectant Towels with Bleach disposable wipes (EPA Reg. No: 56392-8) were effective in reducing the risk of worst-case vaginal test articles. The test articles are considered successfully disinfected as the recovered log reduction for each test article was equal to or greater than 6 for each test replicate.

Performance Testing – Bench: Determination of the performance of the Pelvital System was carried out through Radial Compression Tests; Probe Insertion, Extraction and Probe Cable Pull Tests; and, Display and Control Unit Connector Pull Tests.

Usability Testing: Several ergonomic factors were tested with users. The studies show that users find Pelvital System to be easy to use and that the ergonomic factors designed into the system reduce user error through easy to understand language. The usability testing and results were considered in the Risk Analysis. As problems were identified, both software and mechanical changes were made.

ISTA 6-FEDEX-A Transportation & Packaging: Testing demonstrated compliance with ISTA 6-FedEx A, Testing Packaged Products Weighing up to 150 Lbs.

Risk Analysis - Formal Risk Assessment of the Pelvital System was performed in accordance with ISO 14971. With respect to perceivable conditions in which the device would be subjected to a worst-case environmental or human error scenario, Pelvital USA, Inc. believes the outcomes of these risks are considered acceptable within the context of ISO 14971, and that all potential risks have been mitigated to the lowest form.

Review of Published Literature on Subject Device: The first clinical study on the Pelvital System was conducted at the University Hospital of Northern Norway. Sixty women with leakage between 5g and 50g demonstrated ability to contract pelvic floor muscles, and stress urinary incontinence (SUI) greater than

one year despite supervised pelvic floor muscle training (PFMT), were enrolled. Nilsen et al. (2017)[1] included a single treatment arm where the subjects performed daily at-home PFMT for 5 minutes over six weeks while using the Pelvital System. The primary endpoint was urine leakage at six weeks. Stress tests for urine leakage were performed with a standardized volume of 3dL saline in the bladder. The women in the study who used the Pelvital System had a high cure rate for their SUI condition, comparable to surgical procedures.

This study represents valid scientific evidence from a well-controlled investigation by qualified experts to further demonstrate that there is reasonable assurance of the safety and effectiveness of the subject device under its conditions of use.

10. Clinical Performance Data

A clinical study was conducted to evaluate the safety and effectiveness of the Pelvital System. The study was a randomized, double-blind, crossover trial of adult women who have been diagnosed with stress urinary incontinence. Subjects were placed into the control arm (PFMT in conjunction with no oscillations) or the treatment arm (PFMT in conjunction with oscillations). Subjects conducted their respective therapy five minutes a day over twelve weeks. After six weeks (primary endpoint), all patients in the control arm crossed over into the treatment arm.

The overall summary of the clinical study is shown:

- Study Design: The study was a randomized parallel-group design, with a one-way cross over from control to treatment at six weeks.
- Study Endpoints: The primary outcome for this study is the improvement in the severity of involuntary urine loss, determined by an improvement in 24-hour pad weight test, from baseline to week 6. Secondary outcomes include incontinence episode frequency and health-related quality of life (PGI-I, I-QOL, ICIQ-UI-SF).
- Study Procedure: All subjects are randomized to either the treatment or control arm. Each arm conducts 5 minutes of training therapy each day and conducts bi-weekly follow-up visits. At six weeks, the control arm is crossed over to treatment, and both arms continue daily training through 12 weeks.
- Number of Patients/Sites: 215 subjects were screened for the study. 71 failed the screen for various inclusion/exclusion criteria, and 144 were randomized into the study, 72 in each control and treatment arms. All 144 subjects were evaluated for the 6-week primary endpoint based on the intent to treat (ITT) population across four clinical sites in the United States.

[1] Nilsen I, Rebolledo G, Acharya G, Leivseth G. Mechanical oscillations superimposed on the pelvic floor muscles during Kegel exercises reduce urine leakage in women suffering from stress urinary incontinence: A prospective cohort study with a 2 - year follow up. Acta Obstet Gynecol Scand. 2018;97:1185–1191. https://doi.org/10.1111/aogs.13412

- Study Treatment: The primary endpoint was at six (6) weeks, with participant duration of twelve (12) weeks.

- Results Effectiveness: Of the 144 evaluated patients, 72 were in the treatment arm, and 72 were in the control arm. The Control arm and the Treatment arm have improved significantly over their baseline values. The Control arm utilized the Pelvital trainer without oscillations. The use of the Pelvital device without oscillations had a beneficial effect on its own as compared to baseline (p = .009), and with oscillations, the Treatment arm data compared to baseline is even more profound (p = .0007). A copy of the primary endpoint analysis is presented below:

Visit	N		Mean + S.D.		p-value
	Tx	C	Tx	C	
Baseline	72	72	43.9 ± 49.7	59.1 ± 98.6	**p=0.96 by Mann Whitney U test**
6 weeks	72	72	28.7 ± 46.1	38.8 ±77.8	
Change			17.0 ± 40.6	20.2 ± 64.0	
Change %			33%	33%	
Baseline to 6 weeks: Paired t-test			**P=0.0007**	**P=0.009**	

- Results Safety: A total of 55 patients (44%) had 89 adverse events in combination with all treatment sessions. There was one serious adverse event (Grade 3) that was deemed unrelated to the study device. All other adverse events were graded severity levels 1 or 2.

Results of the clinical investigation support the safety, effectiveness, and indications for the use of the Pelvital System for the strengthening of the pelvic floor muscles, which has been found to help women with urinary incontinence. The clinical study conclusion confirms that the device is safe and effective as used according to the instructions for use.

11. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics but can be demonstrated as substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) Submission that the differences between the Pelvital System and the predicate device do not raise any different questions regarding its safety and effectiveness. The Pelvital USA, Inc. Pelvital System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.