December 29, 2023

Pelvital USA, Inc.
Pamela Snyder
Correspondent & Consultant
860 Blue Gentian Rd. Suite 200
Eagan, Minnesota 55121

Re: K233362
Trade/Device Name: Flyte Mechanotherapy System (aka Flyte System) (MTI-1.0)
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: December 11, 2023
Received: December 11, 2023

Dear Pamela Snyder:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233362

Device Name

Flyte System

Indications for Use *(Describe)*

The Flyte System is intended for strengthening of the pelvic floor muscles to treat 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

Special 510(k) Submission: Labeling Modification Flyte System

Applicant & Manufacturer

Pelvital USA, Inc.
860 Blue Gentian Rd. Suite 200
Eagan, MN 55121
866-735-8482

Applicant Contact
Lydia Zeller
President & CEO
lydia.zeller@pelvital.com
612-643-9724

Date Prepared: December 29, 2023

Device Identification
Trade names: The Flyte System or Flyte or MTI-1.0.
Common Name: Perineometer
Product Code: HIR
Classification Panel: Obstetrics/Gynecology
Regulation Number: 21 CFR § 884.14251
Classification Name: Perineometer

Legally Marketed Predicate
K212655 Flyte System
The predicate devices have not been subject to a design-related recall.

Device Description

The Flyte System is a repeat use, non-sterile, vaginal device intended to condition and strengthen the pelvic floor muscle (PFM) system. The Flyte System is designed for in-home use to deliver treatment to the pelvic floor muscles during normal Kegel exercises. The product consists of a wand and a hand-held controller. The Flyte wand is placed in the vagina and delivers a series of mechanical vibrations while the pelvic floor muscles are contracting.

The hand-held controller controls the wand, guides the user through the treatment session and provides a visual feedback function to inform the user when the correct muscles are being contracted during a Kegel exercise. The wand provides a resistive surface against which the user can contract the PFM, and houses an electric motor containing an eccentric weight that

generates mechanical oscillations when the motor is running. A cable connects the wand and the controller.

Controller: The controller consists of a 3.7V Lithium-ion Polymer rechargeable battery with a capacity of 700-750 mAh and built-in safety protection. The controller also contains a PCB assembly used to control the motor speed and frequency and to provide the user with visual feedback information. The controller housing is made of ABS plastic (Acrylonitrile-butadiene-styrene copolymer).

Wand: The wand contains an accelerometer and gyroscope which enable the Controller to generate the visual feedback information. It also houses the motor and weight used to generate the mechanical vibrations. The wand is available in Large and Small sizes. The wand housing is cylindrical and is made of ABS plastic. The wand 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.

Additional Components:

Charging Cable: Connects the Controller to the Charging Block
Charging Block: AC adapter that allows you to plug the Controller into a wall outlet for charging.

Indications for Use

The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with stress urinary incontinence.

Substantial Equivalence Summary

The Special 510(k) is a Labeling Modification to the Flyte System, predicate K212655. There are no changes to the Flye System device or principles of operation. The predicate and subject device are identical. A summary of the technological feature comparison is included in the SE table for completeness.

	K233362 Under review	Predicate K212655	Comparison
Trade/Device Name	Flyte or Flyte System or Flyte MTI-1.0.System	Flyte or Flyte System or Flyte MTI-1.0. System	Identical
Manufacturer	Pelvital USA, Inc	Pelvital USA, Inc	Same Manufacturer
510(k) Number	K233362	K212655	Same device
Regulation Number	21 CFR § 884.1425	21 CFR § 884.1425	Identical
Regulation Name	Perineometer	Perineometer	Identical
Regulatory Class	II	II	Identical
Product Code	HIR	HIR	Identical

	K233362 Under review	Predicate K212655	Comparison
Over the Counter (OTC)	Yes	Yes	Identical Rx use was removed
Intended Use	Intended for strengthening of the pelvic floor muscles	Intended for strengthening of the pelvic floor muscles	Identical
Indications for Use	The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with stress urinary incontinence	The Pelvital System is intended for the strengthening of the pelvic floor muscles, which has been found to help women with stress urinary incontinence.	Similar Same population Same disease or condition it treats. Same intended use
Target Population	Women with urinary incontinence	Women with urinary incontinence	Identical
Anatomical Site	Vagina-Pelvic floor muscles	Vagina-Pelvic floor muscles	Identical
Single Patient Device	Yes	Yes	Identical
Single Use or Reusable	Reusable	Reusable	Identical
Sterility	Non-Sterile; Clean	Non-sterile; Clean	Identical
Device Design	A handheld Controller and a vaginally inserted Wand	A handheld control unit and a vaginally inserted Wand	Identical Component name changes from Control unit/ Biofeedback unit to Controller
Flyte Components	Wand Controller Charging Cable Charging Block	Wand Control Unit/ Biofeedback Unit Charging Cable Wall Charger	Identical Device Component name change from Control unit to Controller
Visual feedback Display	Yes	Yes	Identical

	K233362 Under review	Predicate K212655	Comparison
Wand Dimensions	SMALL: Max Shaft Diameter: 29 mm Length: 97.85 mm Weight: 89 +/- 1g LARGE: Max Shaft Diameter: 35 mm Length:101 mm Weight: 99+/- 2g	SMALL: Max Shaft OD: 29 mm Length: 97.85 mm Weight: 89 +/- 1g LARGE: Max Shaft Diameter: 35 mm Length:101 mm Weight: 99+/- 2g	Identical
***Technological Characteristics**: The Devices are the Identical. There are No changes to the device.*			

The changes that are the subject of this premarket notification are limited to minor changes to the indication for use statement and labeling. The Flyte System is substantially equivalent to the predicate, Flyte System K212655. The devices are manufactured by Pelvital USA, Inc. There are no changes to the device's technological characteristics, materials, or principles of operation. The devices are identical.

The Flyte System has the same intended use and the same technological characteristics as the previously cleared predicate device, K212655. The Indication for use clarifies the indication without affecting the substance or meaning of the indications or intended use. It does not alter the original intended use or therapeutic effect. There is no change to patient populations, demographics, diagnosis, prognosis, comorbidities, and/or potential for complications. The risk-based assessment included an analysis of both safety and effectiveness. The modifications do not increase the risk profile of the device. There are no changes to contraindications, warnings, or precautions. There are no new risks are modifications of risks.

Clinical and Non-clinical Performance Testing

Given the changes proposed in this submission were limited to minor labeling changes, no clinical and non-clinical performance data was submitted in this submission to support the changes.

Conclusion

The differences do not raise any different questions regarding safety and effectiveness. The Flyte System, as designed and manufactured, is substantially equivalent to the predicate device, K212655 Flyte System.