August 1, 2024

Pelvital USA, Inc.
% Ming Cheng Chew
Regulatory Consultant
Rqm+
2790 Mosside Blvd, #800
Monroeville, Pennsylvania 15146

Re: K240805
Trade/Device Name: Flyte Mechanotherapy System, MTI-1.5 (MTI-1.5)
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: March 22, 2024
Received: July 1, 2024

Dear Ming Cheng Chew:

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,

Sharon M. Andrews -S

For
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)*

K240805

Device Name

Flyte System, MTI-1.5 (MTI-1.5)

Indications for Use *(Describe)*

The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with mild, moderate, and severe 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1 Traditional 510(k) Summary

Contact Information

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Date prepared: August 1, 2024

Device Information

Name of Device:	Flyte System (MTI-1.5)
Common or Usual Name:	Perineometer
Classification Name:	Perineometer
Regulation Number:	21 CFR 884.1425
Regulatory Class:	II
Product Code:	HIR (Perineometer)

Predicate Device

Flyte System (MTI-1.0), K233362

Note: the predicate device has 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 to treat women with urinary incontinence. 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 an intravaginal wand and a hand-held controller. The Flyte wand is placed in the vagina and, under the direction of the controller,

delivers a series of mechanical vibrations while the pelvic floor muscles are contracting. This treatment is called mechanotherapy.

The Flyte controller controls the wand, guides the user through the treatment session and provides visual information to inform the user when the correct muscles are being contracted during a Kegel exercise. The wand is designed to make optimal contact within the vaginal canal and to deliver vibrations via an eccentric weight driven by an electric motor which causes the wand to oscillate at a specific frequency as directed by the controller. The wand additionally provides a resistive surface against which the user can contract the PFM. 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 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 visual information. It also houses the motor and weight used to generate 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.

Optional Flyte App and Provider Portal:
The Flyte App is a mobile application that provides an optional additional interface for the user. The Flyte App enables the user to create an account, pair the App with the Controller, and view general Flyte information and instructions. The Controller provides information to the App, unidirectionally. During a treatment session, the Flyte App provides an optional additional interface guiding the user through the treatment session and providing information to inform the user when correct muscles are being contracted and relaxed during the session. The Flyte App also collects two patient reported outcomes surveys at regular intervals over the treatment period. The Flyte App enables the user to view treatment history, including dates a treatment session was completed, contraction and relaxation data from those sessions, and the patient reported outcomes data. The Flyte App stores data in an encrypted database on the device, and securely uploads data to a secure, HIPAA-compliant cloud database. The Flyte App is not required for use of the Flyte System.

The Flyte Provider Portal is a HIPAA-compliant web portal that enables providers to send invitations to users/patients for Flyte App registration. If a user accepts the provider's

invitation and provides consent during registration, the Flyte Provider Portal enables the provider to view historical treatment and patient reported outcomes data for that user. The Flyte Provider Portal is not required for use of the Flyte System.

INDICATIONS FOR USE

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1-1: Device Comparison to the Predicate Device

Characteristic	MTI-1.5 (Subject Device)	MTI-1.0 (K233362)
Intended Use	Intended for the strengthening of the pelvic floor muscles for the treatment of urinary incontinence	Same
Indication for Use	The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with mild, moderate, and severe, stress urinary incontinence	The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with stress urinary incontinence
Product Code	HIR	Same
Regulation Number	21 CFR 884.1425	Same
Prescription or OTC	OTC	Same
Anatomical Site	Vagina-Pelvic floor muscles	Same
Target Population	Women with urinary incontinence	Same
Single Use	Reusable, single patient	Same
Device Design	A handheld Controller and a vaginally inserted Wand	Same
Physical Components	Wand Controller Charging Cable	Same

Characteristic	MTI-1.5 (Subject Device)	MTI-1.0 (K233362)
	Charging Block	
Reprocessing	Controller Only - The MTI-1.5 controller can be reprocessed by the manufacturer or the manufacturer's agent	None
Sterility	Clean, Non-Sterile	Same
Electrical Safety	IEC 60601-1 series as applicable	Same
Power Source	Rechargeable lithium polymer batter (710 mAh, 3.7V) with USB charging	Same
Mobile Application and Provider Portal	Yes, optional	No
Connectivity	Bluetooth	No
Biocompatibility	ISO 10993-1	Same

The subject and predicate device have the same intended use. As shown in the table above, there are differences in the technological characteristics between the subject and predicate device; however, these differences do not raise different questions of safety or effectiveness.

NON-CLINICAL PERFORMANCE DATA

A high-level summary of the testing conducted to confirm the safety and efficacy of the MTI-1.5 is as follows:

- Dimensional
- Radial Compression (Leveraged from K233362)
- Battery Depletion (Leveraged from K233362)
- Extraction and Probe Cable Pull (Leveraged from K233362)
- Probe Insertion Force (Leveraged from K233362)
- Wand Compression
- Accelerometer functionality
- Therapy Timing
- Low battery and charging
- Motor Rotation Speed
- Post-Treatment Temperature
- Packaging (Leveraged from K233362)
- Software and cybersecurity Testing
- EMC Testing per per IEC 60601-1-2:2014+AMD1:2020 CSV EMC

- Electrical Safety Testing per IEC 60601-1:2005/A1:2012 Safety
- Shelf Life (Leveraged from K233362)
- Biocompatibility (Leveraged from K233362)

Clinical Data

This multi-center, prospective, double-blinded, randomized clinical trial[1] examined the clinical benefits of the Pelvital Flyte® Mechanotherapy System, which provides mechanical therapy superimposed on the pelvic floor muscles (PFM) during voluntary contractions and relaxations of the PFM. The trial (n=119 subjects) compared device treatment with mechanical pulses (vibrations) (Arm A, Parts 1 and 2 Therapy) for 12 weeks to treatment without mechanical pulses (Arm B, Part 1 Therapy only) for the first 6 weeks, after which Arm B participants crossed over to Arm A to receive two-part therapy for the second 6 weeks. Baseline Severity was defined as follows based on 24-hour pad weight: Mild 10-20g, Moderate 21-70g, Severe >70g. In the study cohort, there were 43 participants with mild, 57 with moderate, and 18 with severe baseline incontinence.

The study hypothesis was that use of the Flyte mechanotherapy device with or without mechanical pulses would improve outcomes as compared to baseline, and that therapy with mechanical pulses in conjunction with PFMT would quantitatively improve urinary incontinence as compared to PFMT without device pulses.

The primary efficacy endpoint was the change in the severity of involuntary urine loss, determined by an improvement in 24 Hour pad weight (24-HR PW) from Baseline to week 6.

Secondary endpoints included 24-HR PW at 12 weeks, 24-HR PW for the full cohort from baseline to 6 and 12 weeks, and changes in quality of life (QoL) from Baseline to 6 and 12 weeks using validated, disease-specific instruments [International Consultation on Incontinence Questionnaire – Urinary Incontinence - Short Form (ICIQ-UI-SF) and Urinary Incontinence Quality of Life (I-QOL)]. Subject adherence to treatment was also assessed at 6 and 12 weeks. Voluntary follow-up was continued for up to 24 months.

A reduction in 24-hour pad weight occurred among all participants from baseline to 6-weeks ($P<0.001$) and to 12-weeks ($P<0.001$). Of participants, 57% (68/119) had a >50% reduction in 24-hour pad weight in the first 6 weeks, and 71% (81/114) achieved a clinically meaningful reduction (>50%) in pad weight by 12 weeks of therapy. The median reduction in 24-HR PW was 68% by 12 weeks. Overall, 61% of participants achieved continence with <10g. The median pad weight at 12 weeks for the 71% achieving a clinically meaningful reduction was 5.3g.

Two-part mechanotherapy significantly improved 24-HR PW and QoL across all severities of SUI. Improvements were noted in as little as 2 weeks and appeared to be sustained through 2-year follow up.

The incidence of AEs did not differ greatly between arms. The safety outcomes did not differ by SUI severity group.

[1] Nakib N, Sutherland S, Hallman K, Mianulli M, R Boulware D. Randomized trial of mechanotherapy for the treatment of stress urinary incontinence in women. Therapeutic Advances in Urology. 2024;16. doi:10.1177/17562872241228023

SUBSTANTIAL EQUIVALENCE

Based on the non-clinical and clinical data submitted, the Flyte System (MTI-1.5) is found to be substantially equivalent to the predicate device. The supporting bench and clinical data support the expansion of the indications for use without raising different questions of safety and effectiveness. Additionally, the addition of the mobile app and provider portal, and the new reprocessing instructions to reprocess the MTI-1.5 controller by the manufacturer or its agent do not raise any different questions of safety and effectiveness.

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, K233362 Flyte System.