April 17, 2026

PonteMed AG
℅ Adrienne Lenz
Principal Medical Device Regulatory Expert
Hyman, Phelps, & McNamara, P.C.
700 Thirteenth St, N.W.
Suite 1200
Washington, District of Columbia 20005

Re: K252334
Trade/Device Name: PELVIPOWER Pelvic Functional Magnetic Stimulation (PELVIPOWER PelvicFMS) (033-0-1100-02)
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: March 18, 2026
Received: March 18, 2026

Dear Adrienne Lenz:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252334

Device Name
PELVIPOWER Pelvic Functional Magnetic Stimulation (PELVIPOWER PelvicFMS) (033-0-1100-02)

Indications for Use *(Describe)*

The PELVIPOWER Pelvic Functional Magnetic Stimulation Device (PELVIPOWER PelvicFMS) is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of strengthening and rehabilitating weak pelvic muscles and restoring neuromuscular control for the treatment of male and female 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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K252334
510(K) SUMMARY

1. SUBMITTER INFORMATION

510(k) Submitter:	PonteMed AG
Address:	Stickereistrasse 4 9320 Arbon Switzerland
Applicant Contact Person:	Dr. Remo Schneider CEO Phone: +41 71 333 60 7 E-Mail: schneider@pontemed.com
Correspondent Contact:	Ms. Adrienne Lenz Hyman, Phelps, & McNamara, P.C 1101 K St, N.W.; Suite 700 Washington, DC 200005 United States Phone: (202)737-4292 E-Mail: alenz@hpm.com
Date Summary Prepared:	April 17, 2026

2. DEVICE NAME

Trade Name of the Device:	PELVIPOWER PelvicFMS (033-0-1100-02)
Common Name:	Pelvic floor muscle stimulator
Classification Name:	Stimulator, Electrical, Non-Implantable, For Incontinence
Classification Regulation:	21 CFR 876.5320
Device Class:	Class II
Panel	Gastroenterology/Urology
Product Code	KPI

3. PREDICATE DEVICE

Predicate Devices:	HPM-6000UF
510(k) number	K181497
Company Name	BTL Industries, Inc.

The predicate device has not been subject to a design related recall.

The BTL-398 (K241516) was used as a reference device to support testing of the coil movement feature of the subject device.

4. DEVICE DESCRIPTION

PELVIPOWER PelvicFMS is a non-invasive pelvic floor muscle stimulator device used for the purpose of strengthening, and rehabilitation of weak pelvic muscles and restoration of neuromuscular control. The device produces electromagnetic field impulses that stimulate and strengthen the pelvic floor and surrounding

musculature. The coil under the seat of the PELVIPOWER PelvicFMS chair generates a pulsed magnetic field that elicits muscle contractions in the pelvic floor area. The device is a non-sterile, multi-patient, multi-use device intended for use in health care facilities.

The PELVIPOWER PelvicFMS chair includes an adjustable armrest that can be folded up as necessary to allow easier access for patients with limited mobility (e.g., wheelchair users). To adapt the magnetic field to the patient sitting above it and to achieve an optimal effect, the coil position, the angles of inclination of the seat, and the leg rest are electrically adjustable. The PELVIPOWER PelvicFMS includes a 12" touchscreen display. The on-screen information guides the user throughout the therapy session. The therapeutic parameters can be configured via the touch screen interface. Throughout the therapy session, the device displays therapy information, including the type of therapy, the remaining duration, and key therapy parameters. The chair applicator is made of artificial leather. The PELVIPOWER PelvicFMS chair therapy sessions can be delivered to patients following a pre-set (Automatic Setting) or healthcare professional (HCP)-determined Manual Setting.

5. INDICATION FOR USE

The PELVIPOWER Pelvic Functional Magnetic Stimulation Device (PELVIPOWER PelvicFMS) is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of strengthening and rehabilitating weak pelvic muscles and restoring neuromuscular control for the treatment of male and female urinary incontinence.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Technical Characteristics	**Subject Device** PonteMed AG's PELVIPOWER PelvicFMS [K252334]	**Predicate Device** BTL Industries, Inc.'s HPM-6000UF [K181497]
Indication for use	The PELVIPOWER Pelvic Functional Magnetic Stimulation Device (PELVIPOWER PelvicFMS) is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of strengthening and rehabilitating weak pelvic muscles and restoring neuromuscular control for the treatment of male and female urinary incontinence.	HPM-6000UF is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence.
Function	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation
Type of Energy	Magnetic field	Magnetic field
Stimulation source	Magnetic coil	Magnetic coil
Prescription Use Only	Yes	Yes
Power Source	230 V~, 50–60 Hz, max. 600 VA (2.5 A/230 V) US external transformer: 115/120/125 V~, 50-60Hz, 600 VA The external transformer provided with the system is required for connection to US mains to convert the voltage from 110/115 V to 230 V.	100 – 240 V AC, 50 – 60 Hz, max 14 A
Therapy Process	Specific therapy mode is selected by the clinician based on the patient's symptoms.	Specific therapy mode is selected by the clinician based on the patient's symptoms.
Number of output channels	1	1

Magnetic Field Intensity	0.5 – 2 T	0.7 – 2.5 T
Pulse Repetition Rate	5 to 50 Hz	1 – 150 Hz
Pulse Width	340µs (± 20%)	280 µs (± 20%)
Pulse amplitude adjustment	0-100% in 6 increments	0-100%
Therapy Time	Up to 22 min	Up to 30 min
Interface	Touchscreen	Touchscreen
Firmware controlled	Yes	Yes
Environmental Specifications	Hospital/Clinics only	Hospital/Clinics only
Applicator	Chair	Chair
Applicator (seat) Dimensions	51 x 54 cm (20 x 21 in)	73 x 73 cm (29 x 29 in)
Coil position relative to pelvic floor muscles	Coil adjustment 150mm in horizontal direction	No coil adjustment provided, but patients can be positioned over the center of the coil.

As evidenced by the above table, both the subject and the predicate devices have similar intended use, but the subject and predicate devices have different technological characteristics. The BTL-398 (K241516) was used as a reference device to support testing of the coil movement feature of the subject device which is absent in the predicate. Additionally, performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate do not raise different questions of safety or effectiveness.

7. NON-CLINICAL TESTING

Below is a list of the tests that were performed and successfully completed for the subject device per the following guidance and standards.

- Electrical Safety testing according to IEC 60601-1: 2020 - *Medical electrical equipment – Basic safety and essential performance*
- Electromagnetic Compatibility testing according to IEC 60601-1-2: 2020 - *General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests and* IEC 60601-4-2:2024-*Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic compatibility – Test plan and test report*
- Software Verification and Validation Testing according to FDA's Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*"
- Cybersecurity Verification and Validation Testing according to FDA's Guidance "*Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*"

Additionally, performance bench data was submitted for device performance and durability of the subject device. This data included:

- Verification testing of magnetic stimulation parameters in comparison to the predicate device
- Service life verification test supported by a post-market field study
- Stimulation coil surface temperature rise test (acceptance criterion per ASTM F2182-19E02)
- Magnetic flux density Test to evaluate maximum flux density

All pre-determined acceptance criteria were met.

8. CONCLUSION

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.