February 10, 2025

BTL Industries, Inc.
David Chmel
CEO North America
362 Elm Street
Marlborough, Massachusetts 01752

Re: K241516
Trade/Device Name: Btl-398
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: II
Product Code: KPI
Dated: May 28, 2024
Received: January 8, 2025

Dear David Chmel:

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.

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)*
K241516

Device Name
Btl-398

Indications for Use *(Describe)*
The device 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary

1. Submitter Information

Applicant	BTL Industries, Inc. 362 Elm Street Marlborough, MA 01752 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Official Correspondent	David Chmel BTL Industries, Inc. chmel@btlnet.com
Date Prepared:	February 7, 2025

2. Device Name

Trade/Proprietary Name:	BTL-398
Common Name:	BTL-398
Primary Classification Name:	Nonimplanted electrical continence device
Classification Regulation:	21 CFR 876.5320, Class II
Classification Product Code:	KPI

3. Predicate Device Identification

K181497 HPM-6000UF BTL Industries, Inc.

The predicate device was never subjected to a design related recall.

4. Device Description

The BTL-398 is a non-invasive therapeutic device that delivers magnetic pulses to stimulate the pelvic floor muscles for the treatment of urinary incontinence in adult population. The BTL-398 device is intended for professional use in healthcare facilities as a prescription use only.

The BTL-398 consists of a main unit and a Chair Applicator. The main unit consists of the electromagnetic field generators, the microprocessor-driven control unit, and the touch-screen control panel. The Chair Applicator is designed for non-invasive treatment of urinary incontinence. The magnetic coil is in the center of the seat, and its position is user-adjustable during therapy. Ongoing therapy is indicated by illuminated segments.

The Chair Applicator is designed for precise patient positioning, ensuring the most appropriate posture before and during therapy. Prior to High-Intensity Focused Electromagnetic (HIFEM) therapy, the seat height and coil position can be adjusted using an attached remote controller. The Dynamic HIFEM Technology (DHT) feature ensures the coil is optimally positioned at the right location beneath the patient before starting therapy. At the start of therapy, air is circulated through the seat cushion with the Pressure Wave Technology (PWT) feature (intensity of the PWT function is set based on patient feedback). The PWT feature helps patients maintain the correct therapeutic position during therapy. Both the PWT and DHT features can be readjusted, and the PWT feature can be turned off, at any time during the session. The touch screen display guides the user step-by-step through the entire therapy procedure. During therapy, the screen displays information about the applied therapy, remaining therapy time, and main therapy parameters. Therapy is administered through clothing.

5. Indications for Use

The device 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.

6. Comparison with the Predicate Device

510(k) number	K241516	K181497
Device name	BTL-398	HPM-6000UF
Company name	BTL Industries, Inc.	BTL Industries, Inc.
Type	Subject device	Primary predicate
Product Code and Regulation	Gastroenterology-Urology 21 CFR 876.5320 Nonimplanted Electrical Continence Device KPI - Stimulator, Electrical, Non-Implantable, For Incontinence	Gastroenterology-Urology 21 CFR 876.5320 Nonimplanted Electrical Continence Device KPI - Stimulator, Electrical, Non-Implantable, For Incontinence
Indications for Use	The device 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.	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.
Clinical Use	Prescription Use	Prescription Use
Intended population	Adult Male and Female	Adult Male and Female
Primary Function	Pelvic floor muscle stimulation	Pelvic floor muscle stimulation
Principle of Action	Initiating the action potential of nerves results in muscle contraction	Initiating the action potential of nerves results in muscle contraction
Type of Energy	Magnetic field (Therapy) + air (PWT feature for proper patient positioning)	Magnetic field (Therapy)
Energy Source	100 – 240 V AC, 50 – 60 Hz	100 – 240 V AC, 50 – 60 Hz
Number of output channels	1	1

Magnetic Field Intensity	0.7 – 2.5 T	0.7 – 2.5 T
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz
Pulse Width	280 µs (± 20%)	280 µs (± 20%)
Shape of Stimulation Pulse	Dual-phase, sine pulses	Dual-phase, sine pulses
Therapy Time	Up to 30 min	Up to 30 min
PWT feature	Yes	No
PWT intensity	0-100%	N/A
PWT repetition rate	Up to 40 Hz	N/A
Operating Temperature	+10 to +30 °C (50 – 86 °F)	+10 to +30 °C (50 – 86 °F)
Applicator type	Chair applicator	Chair applicator
Main Unit Dimensions (W×H×D)	580 × 1380 × 580 mm (23 × 54 × 23 in)	500 × 970 × 580 mm (20 × 38 × 23 in)
Applicator Dimensions (W×H×D)	730 x 850 x 730 mm (29 x 33,5 x 29 in)	730 x 730 x 730 mm (29 x 29 x 29 in)
System Weight	99 kg (216 lb)	82 kg (181 lb)
Applicator height adjustment	17 to 22 in (42 to 55 cm)	17 to 22 in (42 to 55 cm)
Coil adjustment (DHT Feature)	Yes 100±5mm in horizontal direction	No
Therapy Modes	• Basic Mode: Frequency: 1-150 Hz, Pulse: 0.01-60 s, Pause: 0-60s, PWT: 1-40 Hz • Sequence Mode: ○ Amplitude modulation with PWT 1-40 Hz ○ Frequency modulation with PWT 1-40 Hz • Single Mode: Frequency: 1-150 Hz, Number of pulses: 1-1000, PWT: 1-40 Hz	• Basic Mode: Frequency: 1-150 Hz, Pulse: 0.01-60 s, Pause: 0-60s • Sequence Mode: ○ Amplitude modulation ○ Frequency modulation • Single Mode: Frequency: 1-150 Hz, Number of pulses: 1-1000

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 differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness. Performance testing was conducted to establish substantial equivalence of the subject device to the predicate device.

7. Summary of Non-clinical Testing

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

- Electrical Safety testing, mechanical strength testing and thermal 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.*
- Software Verification and Validation Testing according to FDA's Guidance (2023) ,*"Content of Premarket Submissions for Device Software Functions | FDA"*

Additionally, performance bench data was submitted for device performance i.e., magnetic field strength testing, coil surface temperature testing/controls and PWT feature testing.

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.