



September 23, 2026

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

Re: K262353

Trade/Device Name: BTL-299-F
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: Class II
Product Code: KPI
Dated: July 10, 2026
Received: July 10, 2026

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 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,

STEPHANIE COLE -S

for

Anthony Lee, Ph.D., M.B.A.

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262353

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Please provide the device trade name(s).

?

BTL-299-F

Please provide your Indications for Use below.

?

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.

The device is intended to provide electromagnetic stimulation for the treatment of fecal incontinence in male and female patients.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary

K262353

General Information

Sponsor: BTL Industries, Inc.
362 Elm Street
Marlborough, MA 01752
Tel: [+1-866-285-1656](tel:+1-866-285-1656)
Fax: +1-888-499-2502

Applicant: BTL Industries, Inc.
362 Elm Street
Marlborough, MA 01752
Tel: [+1-866-285-1656](tel:+1-866-285-1656)
Fax: +1-888-499-2502

Contact Person: David Chmel
BTL Industries, Inc.
chmel@btlnet.com

Summary Preparation
Date: July 3, 2026

Device

Trade/Proprietary Name: BTL-299-F
Common Name: Stimulator, Electrical, Non-Implantable, For Incontinence
Primary Classification Name: Nonimplanted electrical continence device
Classification Regulation: 21 CFR 876.5320, Class II
Classification Product Code: KPI

Legally Marketed Predicate/Reference Devices

The BTL-299-F is substantially equivalent to the following predicate device that is already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

Predicate Device:

HPM-6000UF

Original 510(k) Sponsor: BTL Industries, Inc.

510(k) Number: K181497

Reference Device:

INTONEMV

Original 510(k) Sponsor: InControl Medical, LLC

510(k) Number: K134020

Product Description

The BTL-299-F is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with tissues of the human body. The electromagnetic field delivered in the muscular or neuronal tissue area is triggering stimulation and tonisation.

The BTL-299-F consists of a main unit and one connected applicator. The main unit is equipped with a color touchscreen with a wide viewing angle, which significantly facilitates use of the device. The on-screen information guides the user step by step through the entire therapy procedure.

The therapeutic parameters can be set using the touchscreen, buttons, and knob on the device. During therapy, the device displays information about the applied therapy, the remaining therapy time, and the main therapy parameters. Therapy is applied through clothing.

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.

The device is intended to provide electromagnetic stimulation for the treatment of fecal incontinence in male and female patients.

Technological Characteristics

The BTL-299-F is identical in design to the HPM-6000UF predicate device. The only difference compared to this predicate device is the expansion of the indications for use statement.

The BTL-299-F and its predicate device consist of a main unit and an applicator. The main unit includes an electromagnetic field generator, a computer, and the touchscreen control panel. The applicators are designed for non-invasive treatment of incontinence. The stimulation coil is located in the center of each applicator and is air-cooled. The chair applicator is designed for a therapy of muscles in targeted area.

The coil is located in the middle of the seat and air cooled. For precise patient positioning the seat height can be electronically adjusted.

Non-clinical Testing (Performance, Bench Testing)

The BTL-299-F has been thoroughly evaluated for electrical safety. The device has been found to comply with applicable medical device safety standards:

IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 62304	Medical device software – Software life cycle processes
ISO 14971	Medical devices – Application of risk management to medical devices
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Bench testing, conducted during final quality control of each unit, verified the maximum load capacity of the chair applicator 330 lb (150 kg).

Clinical Testing

To demonstrate the comparability of electromagnetic stimulation with voluntary effort and electrical stimulation of neuromuscular tissue, a clinical experiment was conducted to evaluate the device's ability to non-invasively induce anal sphincter contractions comparable to voluntary effort.

The results demonstrate that the device is capable of activating the anal sphincter muscles via electromagnetic stimulation. These findings support the potential use of electromagnetic stimulation as a method for stimulation muscles in the rectal region.

Comparison with the Predicate Device

510(k) number	K262353	K181497	K134020
Device name	BTL-299-F	HPM-6000UF	InToneMV
Company name	BTL Industries, Inc.	BTL Industries, Inc.	InControl Medical, LLC
	<u>Subject device</u>	<u>Predicate device</u>	<u>Reference device</u>
Product Code and Regulation	<u>Gastroenterology-Urology Devices</u> 21 CFR 876.5320 KPI – Stimulator, Electrical, Non-Implantable, For Incontinence	<u>Gastroenterology-Urology Devices</u> 21 CFR 876.5320 KPI – Stimulator, Electrical, Non-Implantable, For Incontinence	<u>Gastroenterology-Urology Devices</u> 21 CFR 876.5320 KPI – Stimulator, Electrical, Non-Implantable, For Incontinence
Intended 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. The device is intended to provide electromagnetic stimulation for the treatment of fecal incontinence in male and female patients.	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.	InToneMV is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for the treatment of male and female urinary and fecal incontinence.
Clinical Use	Prescription Use	Prescription Use	Clinic or home use, under direction of physician
Applicable Patients	Man and Woman	Man and Woman	Man and Woman
Primary Function	Muscle stimulation	Muscle stimulation	Muscle stimulation

Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction
Type of Energy	Magnetic field	Magnetic field	Direct Electrical stimulation
Energy Source	100 – 240 V AC, 50 – 60 Hz	100 – 240 V AC, 50 – 60 Hz, max 14 A	4/5 AA nickel metal hydride battery
Number of Output Channels	1	1	1
Magnetic Field Intensity	0.7 – 2.5 T	0.7 – 2.5 T	N/A
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	0 - 50 Hz
Pulse Width	280 μ s ($\pm$ 20%)	280 μ s ($\pm$ 20%)	200 μ s
Shape of Stimulation Pulse	Biphasic, sine	Dual phase, rectangular pulses	Dual phase, rectangular pulses
Number of Applicators	2	1	1
Therapy Time	Up to 30 min	Up to 30 min	Up to 30 min
Interface	Touch-screen	Touch-screen	Buttons accompanied by simple screen
Firmware Controlled	Yes	Yes	Yes
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only
Operating Temperature	+10 to +30 °C (50 – 86 °F)	+10 to +30 °C (50 – 86 °F)	Unknown
Main Unit Dimensions (W×H×D)	500 × 970 × 580 mm (20 × 38 × 23 in)	500 × 970 × 580 mm (20 × 38 × 23 in)	122 x 61 x 30 mm (4.8 x 2.4 x 1.1 in)
Main Unit Weight	46 kg (101 lb)	46 kg (101 lb)	Unknown

Substantial Equivalence

The technological characteristics of BTL-299-F are the same as its predicate device HPM-6000UF device. The differences between the predicate, reference and BTL-299-F devices have no significant influence on safety and effectiveness of the BTL-299-F. Therefore, the BTL-299-F is substantially equivalent to the predicate devices.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-299-F device has been shown to be substantially equivalent to currently marketed predicate devices.