



November 14, 2018

BTL Industries, Inc.
David Chmel
VP of Operations
362 Elm Street
Marlborough, MA 01752

Re: K181497
Trade/Device Name: HPM-6000UF
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted Electrical Continance Device
Regulatory Class: II
Product Code: KPI
Dated: September 21, 2018
Received: September 26, 2018

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K181497

Device Name
HPM-6000UF

Indications for Use (Describe)

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.

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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510(k) Summary

General Information

Sponsor: BTL Industries, Inc.
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Fax: +1-888-499-2502

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

Summary Preparation
Date: November 13, 2018

Device Name

Trade/Proprietary Name: HPM-6000UF
Primary Classification Name: Nonimplanted electrical continence device
Common Name: Pelvic floor muscle stimulator
Classification Regulation: 21 CFR 876.5320, Class II
Classification Product Code: KPI

Legally Marketed Predicate Devices

The HPM-6000UF is a non-invasive therapeutic device, and is substantially equivalent to the current products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

Primary predicate - HPM-6000U (K162010)
Secondary predicate - InToneMV (K134020)

Product Description

The HPM-6000UF is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. The electromagnetic field delivered in the muscular or neuronal tissue area is triggering the stimulation and tonisation.

The HPM-6000UF is equipped with a color touch screen with wide view angle that significantly facilitates the use of the device. The on-screen information guides the user step-by-step through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen, buttons and knob on the device. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

Intended Use

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.

Side Effects

The intended use may be accompanied by various side effects such as muscular pain, temporary muscle spasm, temporary joint or tendon pain, temporary increase of local circulation, increased sensitivity during intercourse, and local erythema or skin redness.

Non-clinical Testing

The HPM-6000UF is identical in design to the HPM-6000U predicate. Therefore, no non-clinical testing was needed.

Clinical testing

In order to demonstrate safety of the HPM-6000UF in the treatment of males (specifically, thermal safety to the testes), a clinical study has been conducted. The clinical study documented no meaningful rise in scrotal surface temperature during treatment, and that the HPM-6000UF device is safe in the male population.

Technological Characteristics

The HPM-6000UF is identical in design to the HPM-6000U predicate device. The only difference relative to this predicate device is to expand the indications for use statement.

The HPM-6000UF device and its predicates are comprised of a system console and applicator. The system console consists of the electromagnetic field generators, computer, and the touch-screen control panel. Applicator Chair is designed for non-invasive therapy of urinal incontinence. The coil is located in the middle of the seat and air cooled. Running

therapy is indicated by illuminated segments in armrests. For precise patient positioning prior to the therapy, the seat height can be electronically adjusted by a remote control.

The HPM-6000UF device is using a magnetic field in order to induce neuromuscular tissue stimulation. The InToneMV predicate device is stimulating neuromuscular tissue via the direct current flow. In both cases there is an induction of electrical stimulus in the neuromuscular tissue resulting in the muscle contraction.

The HPM-6000UF device is intended for professional use as a prescription use only, while the InToneMV predicate device is intended also for a home use. The energy source of the HPM-6000UF device is electric power grid instead of battery source by the InToneMV predicate device. Further, the HPM-6000UF is equipped with larger colorful touch-screen control panel to increase user comfort.

The technological differences between the HPM-6000UF device and the predicate devices do not raise any new types of safety or effectiveness questions.

510(k) number Device name Company name	Not Assigned HPM-6000UF BTL Industries, Inc.	K162010 HPM-6000U BTL Industries, Inc.	K134020 InToneMV InControl Medical, LLC
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	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.	HPM-6000U 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 urinary incontinence in women.	InToneMV is intended to provide electrical stimulation and/or visual biofeedback (via manometry) for treatment of male and female urinary and fecal incontinence.

510(k) number	Not Assigned	K162010	K134020
Device name	HPM-6000UF	HPM-6000U	InToneMV
Company name	BTL Industries, Inc.	BTL Industries, Inc.	InControl Medical, LLC
Clinical Use	Prescription Use	Prescription Use	Clinic or home use, under direction of physician
Applicable Patients	Male and Female	Woman	Male and Female
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	Electrical
Energy Source	100 – 240 V AC, 50 – 60 Hz, max 14 A	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	Dual phase, rectangular pulses	Dual phase, rectangular pulses	Dual phase, rectangular pulses
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

510(k) number	Not Assigned	K162010	K134020
Device name	HPM-6000UF	HPM-6000U	InToneMV
Company name	BTL Industries, Inc.	BTL Industries, Inc.	InControl Medical, LLC
Software Level of Concern	Moderate	Moderate	Moderate
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only
Feedback	By Patient	By Patient	Manometric air pressure
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)
Applicator Dimensions (W×H×D)	730 x 730 x 730 mm (29 x 29 x 29 in)	730 x 730 x 730 mm (29 x 29 x 29 in)	196 x 58 x 99 mm (7.7 x 2.3 x 3.9 in)
System Weight	46 kg (101 lb)	46 kg (101 lb)	Unknown

Substantial Equivalence

Based upon the intended use and known technical information provided in this pre-market notification, the HPM-6000UF device has been shown to be substantially equivalent to currently marketed predicate devices.

Conclusion

Based on the aforementioned information, the HPM-6000UF is safe and effective and substantially equivalent to the identified predicate devices.