DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 13, 2016

BTL Industries, Inc.
% Jan Zarsky
Director
47 Loring Drive
Framingham, MA 01702

Re: K162010
Trade/Device Name: HPM-6000U
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted Electrical Continence Device
Regulatory Class: Class II
Product Code: KPI
Dated: September 15, 2016
Received: September 16, 2016

Dear Jan Zarsky,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Not known
K162010

Device Name
HPM-6000U

Indications for Use *(Describe)*
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.

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.

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BTL Industries

510(k) Summary

General Information

Sponsor:	BTL Industries, Inc. 47 Loring Drive Framingham, MA 01702 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Applicant:	BTL Industries, Inc. 47 Loring Drive Framingham, MA 01702 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Contact Person:	Jan Žársky Director BTL Industries, Inc. zarsky@btlnet.com
Summary Preparation Date:	July 19, 2016

Device Name

Trade/Proprietary Name:	HPM-6000U
Primary Classification Name:	Stimulator, Electrical, Non-Implantable, For Incontinence
Classification Regulation:	21 CFR 876.5320, Class II
Classification Product Code:	KPI

Legally Marketed Predicate Devices

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

Neotonus Model 1000 Muscle Stimulator System (K973096)

Product Description

The HPM-6000U 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-6000U 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-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.

Non-clinical Testing

The HPM-6000U device has been thoroughly evaluated for electrical safety. The HPM-6000U has been found to comply with the following applicable medical device safety standards:

ISO 14971	Medical devices – Application of risk management to medical devices
IEC 62304	Medical device software – Software life cycle processes
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 compatibility – Requirements and tests
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Clinical testing

The substantial equivalence determination for the HPM-6000U is not based on clinical testing. The device safety and efficacy was demonstrated by comparison of technical characteristics between the HPM-6000U and the predicate device.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**Not Assigned** HPM-6000U BTL Industries, Inc.	**K973096** Neotonus Model 1000 Muscle Stimulator System Neotonus, Inc.
Product Code and Regulation	Gastroenterology-Urology Devices 21 CFR 876.5320 KPI – Stimulator, Electrical, Non-Implantable, For Incontinence	Gastroenterology-Urology Devices 21 CFR 876.5320 KPI – Stimulator, Electrical, Non-Implantable, For Incontinence
Intended Use	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.	Neotonus Model 1000 Muscle Stimulator System 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.
Primary Function	Stimulation of pelvic floor musculature	Stimulation of pelvic floor musculature
Principle of Action	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
Energy Source	100 – 240 V AC, 50 – 60 Hz, max 14 A	110 V AC, 50 – 60 Hz, max 12 A
Type of Coil	Single magnetic coil	Single magnetic coil
Number of	1	1

510(k) number **Device name** **Company name**	**Not Assigned** HPM-6000U BTL Industries, Inc.	**K973096** Neotonus Model 1000 Muscle Stimulator System Neotonus, Inc.
Magnetic Coils in the Applicator		
Type of Applicator	Chair	Chair
Number of Applicators	1	1
Patient Position during Therapy	Sitting position	Sitting position
Position of Coil	Center of applicator seat	Center of applicator seat
Type of Operation	Continuous	Continuous
Magnetic Field Intensity	0.7 – 2.5 T	Up to 2.2 T
Pulse Repetition Rate	1 – 150 Hz	1 – 55 Hz
Step of Frequency Setting	1 Hz	1 Hz
Pulse Duration	280 µs (± 20%)	275 µs
Pulse Amplitude	0 – 100 %	0 – 100 %
Shape of Stimulation Pulse	Sine, biphasic	Sine, biphasic
Therapy Time	30 min	30 min
Operating Temperature	+10 to +30 °C (50 – 86 °F)	+10 to +30 °C (50 – 86 °F)
Interface	Touch-screen	Graphical Display
Firmware controlled	Yes	Yes
Environmental Specifications	For indoor use only	For indoor use only
Clinical Use	Prescription Use	Prescription Use

510(k) number	**Not Assigned**	**K973096**
Device name	HPM-6000U	Neotonus Model 1000 Muscle Stimulator System
Company name	BTL Industries, Inc.	Neotonus, Inc.
External Exchangeable Fuse	Yes	Yes
Main Unit Dimensions (W×H×D)	500×970×580 mm (20×38×23 in)	580×170×320 mm (23×7×12.5 in)
Applicator Dimensions (W×H×D)	730x730x730 mm (29x29x29 in)	700x1250x785 mm (27.5x49x31 in)
System Weight	46 kg (101 lb)	42.5 kg
Position	Vertical – On castors	Horizontal
Electrical Protection	Class II, BF	Class II

Substantial Equivalence

Based upon the intended use and known technical information provided in this pre-market notification, the HPM-6000U device has been shown to be substantially equivalent to currently marketed predicate device. Thorough Substantial Equivalence Discussion is provided in Section 12.

Conclusion

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