DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 21, 2016

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

Re: K160992
Trade/Device Name: HPM-6000
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: March 21, 2016
Received: April 8, 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 yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.10.21 16:12:18 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K160992

Device Name
HPM-6000

Indications for Use *(Describe)*
The HPM-6000 device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The HPM-6000 device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

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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510(k) Summary
K160992/S001

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 Zarsky Director BTL Industries, Inc. zarskyj@btlnet.com
Summary Preparation Date:	October 21, 2016

Device Name

Trade/Proprietary Name:	HPM-6000
Primary Classification Name:	Stimulator, Muscle, Powered
Classification Regulation:	21 CFR 890.5850, Class II
Classification Product Code:	IPF

Legally Marketed Predicate Devices

The HPM-6000 is a state-of-the-art magnetic device with accessories, and is substantially equivalent to its predicate that is already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

- Neotonus MS-101 Magnetic Muscle Stimulator System (K973929)

Product Description

The HPM-6000 is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body, while mainly affected structures are muscular, collagenous, and neuronal tissue. The electromagnetic field is delivered in the subdermal, muscular or collagenous tissue area triggering the stimulation and relaxation. The subject device does not use electroconductive media.

The HPM-6000 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

The HPM-6000 device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The HPM-6000 device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Non-clinical Testing

The HPM-6000 device has been thoroughly evaluated for electrical safety. The HPM-6000 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
IEC 62366	Medical devices - Application of usability engineering to medical devices
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-6000 is not based on clinical testing. The device safety and efficacy was demonstrated by performance data and comparison of technical characteristics between the HPM-6000 and the predicate device.

Summary of Clinical and Non-clinical testing

Nonclinical test have been conducted to evaluate the HPM-6000 performance, and results confirm that the device performs as intended and in a similar manner compared to the predicate. Thus, the HPM-6000 is substantially equivalent to the predicate devices.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K160992** HPM-6000 BTL Industries, Inc.	**K973929** Neotonus MS-101 Magnetic Muscle Stimulator System Neotonus, Inc.	**Discussion**
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered	**None**
Intended Use	The HPM-6000 device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The HPM-6000 device is indicated for use in stimulating neuromuscular tissue for bulk	The Neotonus MS-101 Magnetic Muscle Stimulator System is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Neotonus MS-101 is indicated for use in stimulating	**None**

510(k) number **Device name** **Company name**	**K160992** HPM-6000 BTL Industries, Inc.	**K973929** Neotonus MS-101 Magnetic Muscle Stimulator System Neotonus, Inc.	**Discussion**
	muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	
Electrical Protection	Class II, BF	Class II	**None**
Interface	Touch-screen	Graphical Display	**Similar, not significantly different**
Type of Energy	Magnetic field	Magnetic field	**None**
Type of Applicator	Single magnetic coil	Single magnetic coil	**None**
Number of Magnetic Coils in the Applicator	1	1	**None**
Number of Applicators	2	1	**None**
Color Touch Screen	8.4 in 21.3 cm 800×400 pixel	Unknown	**N/A**
Type of Operation	Continuous	Continuous	**None**
Pulse Repetition Rate	1 – 150 Hz	1 – 55 Hz	**Similar** Please see the discussion and

510(k) number **Device name** **Company name**	**K160992** HPM-6000 BTL Industries, Inc.	**K973929** Neotonus MS-101 Magnetic Muscle Stimulator System Neotonus, Inc.	**Discussion**
			conclusion below.
Magnetic Field Intensity	299-1 applicator: 0.5 – 1.8 T 299-2 applicator: 0.7 – 2.5 T	Up to 2.2 T	**Similar, not significantly different**
Pulse Duration (±20 %)	280 µs	275 µs	**None**
Pulse Amplitude	0 – 100 %	0 – 100 %	**None**
Therapy Time	Up to 60 min	30, 60 min	**None**
Operating Temperature	10–30 °C	5–30 °C	**Similar, not significantly different**
Operating Humidity	30–75 %	20–75 %	**Similar, not significantly different**
Shape of Stimulation Pulse	Sine, biphasic	Sine, biphasic	**None**
Energy Source	100 – 240 V AC, 50 – 60 Hz, max 14 A	110 V AC, 50 – 60 Hz, 12 A	**None**
External Exchangeable Fuse	Yes	Yes	**None**
System Dimensions (W×H×D)	500×970×580 mm (20×38×23 in)	500×580×230 mm (20×23×9 in)	**Similar, not important for the device safety and effectiveness evaluation**
System Weight	33 kg (73 lb)	28 kg (61 lb)	**Similar, not important for the device safety and effectiveness evaluation**

510(k) number	K160992	K973929	Discussion
Device name	HPM-6000	Neotonus MS-101 Magnetic Muscle Stimulator System	
Company name	BTL Industries, Inc.	Neotonus, Inc.	
Position	Vertical – On castors	Horizontal	**Similar, not important for the device safety and effectiveness evaluation**

The HPM-6000 device has the same indications for use and similar technological characteristics and principles of operation as its predicate device.

One of the technological differences between the subject and predicate devices includes pulse repetition rate. Therefore, K952089, a powered muscle stimulator cleared under the IPF product code (predicate of the predicate or K952089) has been submitted to demonstrate that safety and effectiveness are not adversely affected. K952089 or Rich-Mar CM-II Muscle Stimulator has pulse repetition range rate of 2-200 Hz, compared to 0-150 Hz for HPM-6000, the subject device. The mechanism of action of the electrical stimulator and this kind of magnetic device is the same. The nerve gets stimulated by electrical current and while the method of delivery is the different (magnetic induction), it is still the same current delivered to the tissue that stimulates the nerve endings on a similar frequency.

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

The non-clinical test results confirm that the depth of tissue penetration does not differ and pulse repetition rate works in a similar manner compared to the predicate. Thus, the HPM-6000 is substantially equivalent to the predicate devices.

Substantial Equivalence

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

Conclusion

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