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.**

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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# 510(k) Summary
# K160992/S001

## General Information

| | |
|---|---|
| Sponsor: | BTL Industries, Inc.<br>47 Loring Drive<br>Framingham, MA 01702<br>Tel: +1-866-285-1656<br>Fax: +1-888-499-2502 |
| Applicant: | BTL Industries, Inc.<br>47 Loring Drive<br>Framingham, MA 01702<br>Tel: +1-866-285-1656<br>Fax: +1-888-499-2502 |
| Contact Person: | Jan Zarsky<br>Director<br>BTL Industries, Inc.<br>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 |

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