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

February 16, 2017

BTL Industries, Inc.
David Chmel
Director
47 Loring Drive
Framingham, Massachusetts 01702

Re: K163165
Trade/Device Name: AM-100
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 16, 2017
Received: January 17, 2017

Dear Mr. 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. 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 and Part 809; 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 and Part 809), 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,

Michael J. Hoffmann -S

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)*
K163165

Device Name

AM-100

Indications for Use *(Describe)*

AM-100 is indicated to be used for:
• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.
• Strengthening, Toning and Firming of buttocks and thighs.

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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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:	David Chmel BTL Industries, Inc. chmel@btlnet.com
Summary Preparation Date:	February 16, 2017

Device Name

Trade/Proprietary Name:	AM-100
Primary Classification Name:	Stimulator, Muscle, Powered
Classification Regulation:	21 CFR 890.5850, Class II
Classification Product Code:	NGX

Legally Marketed Predicate Devices

The AM-100 is a state-of-the-art magnetic device with accessories, 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:

- Torc Body (K131291)

The HPM-6000 device was used as a reference device to support the determination of substantial equivalence. The HPM-6000 is cleared (K160992) as a PMS device because it elicits a muscle contraction.

Product Description

The AM-100 is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. By muscle stimulation, the AM-100 helps to strengthen and firm the abdomen, buttocks and thighs.

The AM-100 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.

The AM-100 device has already been cleared by the FDA for muscle stimulation under the device name HPM-6000 (K160992).

Indications for Use

AM-100 is indicated to be used for:

- Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.
- Strengthening, Toning and Firming of buttocks and thighs.

Non-clinical Testing

The AM-100 device has been thoroughly evaluated for electrical safety. The device has been found to comply with the following 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 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 60601-2-10	Medical Electrical Equipment – Part 2-10: Particular Requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators

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