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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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

IEC 62366	Medical devices - Application of usability engineering to medical devices
IEC 62304	Medical device software – Software life cycle processes
ISO 14971	Medical devices – Application of risk management to medical devices

Clinical testing

The substantial equivalence determination for the AM-100 is not based on clinical testing. The device safety and efficacy was demonstrated by comparison of technical characteristics between the AM-100 and the predicate device.

Summary of Clinical and Non-clinical testing

Nonclinical test have been conducted to evaluate the AM-100 performance, and results confirm that the device performs as intended and in a similar manner compared to the predicate. Thus, the AM-100 is substantially equivalent to the predicate devices.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**Not Assigned** AM-100 BTL Industries, Inc.	**K131291** Torc Body Johari Digital HealthCare Ltd.	**Significant Difference**
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 NGX – Stimulator, Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 NGX – Stimulator, Muscle, Powered, Muscle Conditioning	**None**

510(k) number **Device name** **Company name**	**Not Assigned** AM-100 BTL Industries, Inc.	**K131291** Torc Body Johari Digital HealthCare Ltd.	**Significant Difference**
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.	TORC BODY is indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	**None**
Primary Function	Muscle stimulation	Muscle stimulation	**None**
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	**None**
Clinical Use	Prescription use	Home use	**Not Significantly different**
Electrical Protection	Class II, BF	Class II, BF	**None**
User Interface	Touch screen	Touch screen	**None**
Firmware Controlled	Yes	Yes	**None**
Type of Energy	Magnetic field	Electrical	**Not Significantly different**
Magnetic Field Intensity	Applicator 299-1: 0.5–1.8 T Applicator 299-2: 0.7–2.5 T	N/A	**N/A**
Type of Operation	Continuous	Continuous	**None**
Pulse Repetition Rate	1 – 150 Hz	1 - 200 Hz	**Not significantly different**

510(k) number **Device name** **Company name**	**Not Assigned** AM-100 BTL Industries, Inc.	**K131291** Torc Body Johari Digital HealthCare Ltd.	**Significant Difference**
Pulse Duration	280 ± 20% µs	290 µs	**None**
Pulse Amplitude	0 – 100%	0 – 100%	**None**
Current Strength	N/A	Up to 102 mA	**N/A**
Induced Current in the Tissue	28-30 mA	28 mA	**Not significantly different**
Selection of parameters (Intensity, Time)	Yes	Yes	**None**
Therapy Time	Up to 60 min	1 – 60 min	**None**
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Square Wave	**Not significantly different**
Energy Source	100 – 240 V AC, 50–60 Hz	24 V DC Battery pack and Adaptor: 100 – 240 V AC, 50–60 Hz	**Not significantly different**
System Dimensions (W×H×D)	500×970×580 mm (20×38×23 in)	152x102x203 mm (6×4×8 in)	**Not significantly different**
Ambient Temperature	-10°C to +55°C	0°C to +44°C	**Not significantly different**
Environmental Specifications	For indoor use only	For indoor use only	**None**

Substantial Equivalence

The AM-100 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 the predicate device includes type of energy used. However, the mechanism of action of the electrical stimulator and this

kind of magnetic device is the same. Further, the predicate device is intended for a home use, while the subject device is intended for prescription use only. There are devices with a similar technology that are already cleared by the FDA as a prescription use devices. The AM-100 device and its predicate device differ in the shape of stimulation pulse, however that feature does not influence the muscle contraction stimulation. The last technological difference between the subject and the predicate device is pulse repetition rate. The pulse repetition rate of the subject device is within the range of the commonly used ones for devices intended for muscle stimulation.

The energies coming out of the devices can not be directly compared due to the fact the predicate device is a contact one while the subject device is the non-contact device. Comparable are electrical currents induced directly in the targeted tissue.

The current induced by the magnetic field (subject device) is almost identical compared to the predicate device.

The technological differences between the AM-100 and the predicate device do not raise new types of safety or effectiveness questions.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the AM-100 device has been shown to be substantially equivalent to currently marketed predicate device.