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

September 13, 2016

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

Re: K161551
Trade/Device Name: TR-100
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 31, 2016
Received: September 1, 2016

Dear Mr. 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 Part 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 Parts 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,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
n/a K161551

Device Name
TR-100

Indications for Use *(Describe)*
The TR-100 device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The TR-100 massage device is intended to provide a temporary reduction in the appearance of cellulite.

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.

Section 5 – 510(k) Summary

General Information

Sponsor: BTL Industries, Inc.
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Tel: +1-866-285-1656
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Applicant: BTL Industries, Inc.
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Contact Person: Jan Zarsky
BTL Industries, Inc.
Executive VP
zarsky@btlnet.com

Summary Preparation Date: 09 May 2016

Device Names

Trade/Proprietary Name: TR-100

Primary Classification Name: Electrosurgical cutting and coagulation and accessories

Common Name: Combined high frequency and pulsed massager

Classification Regulation: 878.4400

Product Code: PBX

Legally Marketed Predicate Devices

The TR-100 is substantially equivalent to the current product that is already cleared for USA distribution under the following 510(k) Premarket Notification number:

- Exilis XP (K143040).

Product Description

The TR-100 is a state-of-the-art radiofrequency device with integrated massager, that enables the application of therapy by a non-invasive, high-frequency field.

The control unit of the system is fitted with a color touch screen, to facilitate use of the device. The on-screen information guides the operator through the entire therapy. For easier control, the handpiece is equipped with buttons, enabling operation of the device during therapy. The energy flow is indicated by the illuminated treatment tip.

The TR-100 consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic energy generator
- massage generator
- user interface with 8.4” color touch screen
- handpiece

Indications for Use

The TR-100 RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The TR-100 massage device is intended to provide a temporary reduction in the appearance of cellulite.

Non-clinical Testing

The TR-100 device has been thoroughly evaluated for electrical safety. The TR-100 has been found to conform to applicable medical device safety standards. The device complies with the following standards:

ISO 14971	Medical devices – Application of risk management to medical devices
IEC 62304	Medical Device Software – Software Life Cycle Processes
IEC 60601-1	General requirements for safety
IEC 60601-1-2	Electromagnetic compatibility–Requirements and Tests
IEC 60601-2-2	Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories
ISO 10993-1	Evaluation and testing within a risk management process
ISO 10993-5	Biological Evaluation of Medical Devices–Tests for In Vitro toxicity

ISO 10993-10 Biological Evaluation of Medical Devices–Test for Irritation and Skin Sensitization

Clinical testing

The substantial equivalence determination for the TR-100 is based on clinical performance testing. The aim of the performance test was to prove that the device reaches the effective treatment temperature and maintain it for required time.

Comparison with the Predicate Device

Device Name	TR-100	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	n/a	K143040
Regulation	General & Plastic Surgery 21 CFR 878.4400 Electrosurgical cutting and coagulation and accessories	General & Plastic Surgery 21 CFR 878.4400 Electrosurgical cutting and coagulation and accessories
Product Code	PBX	PBX
Indications for Use	The TR-100 device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The TR-100 massage device is intended to provide a temporary reduction in the appearance of cellulite.	The Exilis XP device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The Exilis XP massage device is intended to provide a temporary reduction in the appearance of cellulite.
Device Technologies	Application of the heat to the tissue via RF energy. Massaging of body parts with massage tip.	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment.
Electrical Protection	Class II, BF	Class II, BF
Color Touch Screen	8.4" (215mm) / 640x480 pixel	8.4" (215mm) / 640x480 pixel

Device Name	TR-100	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	n/a	K143040
RF Tip Surface in contact with skin	3.14 cm²	1.13 – 2.54 cm²
Maximum Output Power (Density)	Up to 300 W (95.5 W/cm²)	Up to 120 W (47.2 – 106.2 W/cm²)
Effective Treatment Temperature	40 – 45 °C (104 – 113 °F)	40 – 45 °C (104 – 113 °F)
Skin Temperature Monitoring	Based on Patient's Feedback. Integrated IR thermometer.	Based on Patient's Feedback. Separate IR thermometer.
Heating Energy Type	Radiofrequency	Radiofrequency
Modes of Operation	Monopolar	Monopolar
Output Frequency	0.5 MHz ± 50 kHz	3.25 MHz ± 50 kHz
Waveform	Sinusoid	Sinusoid
Massage Tip Material	Metal	Grey Plastic material
Massage application	Manual Circular, Automatic Vertical	Manual Circular
Material of the Generator Case	Aluminium, Plastic, Stainless Steel	Aluminium, Plastic, Stainless Steel
Handpiece Holder Availability	YES	YES
Patch Electrode	YES	YES
Energy Source	100 - 240 VAC, max 7A, 50-60 Hz	110 - 240 V, max 4A, 50-60 Hz

Device Name	TR-100	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	n/a	K143040
Material of the Generator Case	Aluminum, Plastic, Stainless Steel	Aluminum, Plastic, Stainless Steel
RF Energy Emission Indicator	YES	YES
Dimensions (W x H x D)	600 × 1000 × 600 mm (24” × 39” × 24”)	406 × 270 × 302 mm (15.98” × 10.63” × 11.87”)
Weight	50.7 lb (23 kg)	16 lb (7.3 kg)

Substantial Equivalence

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

Conclusion

Based on the aforementioned information, the TR-100 is safe and effective and substantially equivalent to the identified predicate device.