March 29, 2019

BTL Industries, Inc.
Mr. David Chmel
VP of Operation
362 Elm Street
Marlborough, Massachusetts 01752

Re: K190023
Trade/Device Name: Btl-084
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: December 28, 2018
Received: January 4, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.03.29 07:33:49 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190023

Device Name
BTL-084

Indications for Use *(Describe)*
The BTL-084 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 BTL-084 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.

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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: David Chmel
BTL Industries, Inc.
chmel@btlnet.com

Summary Preparation Date: March 28, 2019

Device Name

Trade/Proprietary Name:	BTL-084
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400, Class II
Classification Product Code:	PBX

Legally Marketed Predicate Devices

The BTL-084 is a state-of-the-art radiofrequency device with integrated massager and 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:

- TR-100 (K161551)

Product Description

The BTL-084 is a non-invasive therapeutic device. The device enables the application of therapy by a 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 BTL-084 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

Intended Use

The BTL-084 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 BTL-084 massage device is intended to provide a temporary reduction in the appearance of cellulite.

Non-clinical Testing

The BTL BTL-084 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 disturbances – 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
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62304	Medical device software – Software life cycle processes
ISO 14971	Medical devices – Application of risk management 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 BTL-084 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.

Technological Characteristics

The BTL-084 device has the same indications for use and similar technological characteristics and principles of operation as its predicate device. The BTL-084 device and its predicate are comprised of a system console and RF applicator with integrated massager. The system console consists of the radiofrequency generator, computer, and the touch-screen control panel. The Essential technical characteristics of the BTL-084 and its predicate device, particularly the type of energy, mode of operation, effective treatment temperature and the safety elements (e.g. skin temperature monitoring) are identical.

Compared to the predicate, the BTL-084 device has lower maximum output power and output frequency, sufficient to reach the effective treatment temperature. The subject device has slightly smaller massage tip and larger RF tip surface to enable treatment of larger area at the same time.

The technological differences between the BTL-084 device and the predicate device do not raise any new types of safety or effectiveness questions.

Substantial Equivalence

The BTL-084 device has the same intended use as its predicate devices. The technological characteristics of the predicate devices are similar to the BTL-084 device. Any differences between the predicate devices and BTL-084 device have no significant influence on safety or effectiveness of the BTL-084 device. Therefore, the BTL-084 device is substantially equivalent to the predicate devices.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-084 device has been shown to be substantially equivalent to currently marketed predicate device.