December 13, 2018

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

Re: K180359
Trade/Device Name: BTL-FR2000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 8, 2018
Received: November 13, 2018

Dear David 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: 2018.12.13 13:27:30 -05'00'

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)*
K180359

Device Name
BTL-FR2000

Indications for Use *(Describe)*
The Applicator 786-1 of BTL-FR2000 device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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See PRA Statement below.

510(k) Number *(if known)*
K180359

Device Name
BTL-FR2000

Indications for Use *(Describe)*
The Applicator 786-2 of BTL-FR2000 device is intended for dermatological procedures requiring fractional treatment of the skin.

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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BTL Industries

510(k) Summary

General Information

Sponsor:	BTL Industries, Inc. 362 Elm Street Marlborough, MA 01752 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Applicant:	BTL Industries, Inc. 362 Elm Street Marlborough, MA 01752 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Contact Person:	David Chmel BTL Industries, Inc. chmel@btlnet.com
Summary Preparation Date:	December 13, 2018

Device

Trade/Proprietary Name:	BTL-FR2000
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400, Class II
Classification Product Code:	GEI

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Legally Marketed Predicate Devices

The BTL-FR2000 is a state-of-the-art radiofrequency device with accessories. The device is substantially equivalent to the products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

- INFINI Radiofrequency System (K121481)
- Matrix RF Applicator (K090025)

Product Description

The BTL-FR2000 device enables 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 button, enabling operation of the device during therapy. Quality of the energy flow is indicated by the illuminated treatment tip.

The BTL-FR2000 device comes with two types of the applicator, depending on the applicator tip attached – Applicator 786-1 and Applicator 786-2.

The BTL-FR2000 device consists of the following main components:

- microprocessor-driven control unit
- radiofrequency generator
- user interface with 8.4” color touch screen
- applicator for an application of radiofrequency
- exchangeable applicator tips

Intended Use

The Applicator 786-1 of BTL-FR2000 device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

The Applicator 786-2 of BTL-FR2000 device is intended for dermatological procedures requiring fractional treatment of the skin.

Performance Data

The BTL-FR2000 device has been thoroughly evaluated for electrical safety. The device has been found to comply with applicable medical device safety standards:

IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

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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 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories
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 11135	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

Bench testing has been performed in order to demonstrate the device is able to achieve required temperature in the treated area.

Technological Characteristics

The BTL-FR2000 device has similar technological characteristics compared to its predicate devices. The BTL-FR2000 device and the predicates are comprised of a system console and applicator(s). The system console consists of the RF generator, computer, and the touch-screen control panel. The applicator is used with exchangeable tips as by predicates.

The energy source of the BTL-FR2000 device is 100 – 240 V AC, 50 – 60 Hz, alike the predicate devices. BTL-FR2000 electrical protection is classified as Class II, BF and it assures high level of electric shock protection.

Type of energy applied is identical to the devices being compared, the electromagnetic energy is used to achieve the intended use. The RF signal frequency of 1 MHz is also identical. The difference between BTL-FR2000 device and predicate devices is in mode of operation. The BTL-FR2000 device use monopolar mode of operation, compared to the bipolar mode by predicate devices. Nevertheless, monopolar mode of operation is also used by devices with similar intended use, cleared by the FDA. Moreover above mentioned bench testing has been conducted to verify the device is able to achieve required temperature in the treated area. Therefore the differences does not rise any new questions of safety nor effectiveness.

The BTL-FR2000 device, as well as the predicate devices, uses sterile exchangeable tips. The material used for production of superficial pins and needles is gold, identical material for the devices being compared. The depth of micro-needle electrodes of BTL-FR2000 device, 0.5 – 3.5mm is also identical to predicate device. The needle spacing of 1.7mm is comparable to the predicate devices. The tips size of compared devices slightly differ, but this difference does not rise any new questions of safety nor effectiveness.

Furthermore, technological differences in the shape and dimensions of the BTL-FR2000 device console and predicate devices also do not raise any safety or effectiveness questions, given that the BTL-FR2000 device console design was previously cleared.

Therefore, the BTL-FR2000 device has similar technological characteristics compared to its predicate devices.

Substantial Equivalence

The BTL-FR2000 device has similar intended use and technological characteristics to the predicate devices. Any differences between the predicate devices and BTL-FR2000 device have no significant influence on safety or effectiveness of the BTL-FR2000 device. Therefore, the BTL-FR2000 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-FR2000 device has been shown to be substantially equivalent to currently marketed predicate devices.