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

January 12, 2017

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

Re: K163176
Trade/Device Name: Exilis XP II
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: December 19, 2016
Received: December 22, 2016

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); 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), 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,

Jennifer R. Stevenson -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)*

K163176

Device Name
Exilis XP II

Indications for Use *(Describe)*

The Exilis XP II 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 Exilis XP II 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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BTL Industries

K163176

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:	27 October 2016

Device Names

Trade/Proprietary Name:	Exilis XP II
Primary Classification Name:	Massager, Vacuum, Radio Frequency Induced Heat
Classification Regulation:	878.4400
Product Code:	PBX

Legally Marketed Predicate Devices

The Exilis XP II system is a state-of-the-art high-frequency energy device with accessories, and 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

Subject of the submission is approval of design changes, improvement of the device ergonomics, hygiene and cleaning through addition of exchangeable and single use applicator tips.

The Exilis XP II is a state-of-the-art radiofrequency device 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. Quality of the energy flow is indicated by the illuminated treatment tip.

Exilis XP II comes with the opportunity of exchangeable tips for patients greater convenience when treating various body parts.

Contact quality monitoring system is present for monitoring of the contact quality under the patch electrode. An easy-to-read handpiece display shows the selected treatment parameters.

The Exilis XP II consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic energy generator
- user interface with 8.4” color touch screen
- applicator for an application of radiofrequency
- exchangeable applicator tips to treat various body parts

Indications for Use

The Exilis XP II 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 Exilis XP II massage device is intended to provide a temporary reduction in the appearance of cellulite.

Non-clinical Testing

The Exilis XP II device has been thoroughly evaluated for electrical safety. The Exilis XP II has been found to conform with applicable medical device safety standards. The system 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

Medical Electrical Equipment
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 Exilis XP II system is not based upon clinical performance testing. The device safety and efficacy was demonstrated by comparison of technical characteristics between the Exilis XP II and compared to the predicate device.

Summary of Clinical and Non-clinical testing

Non-clinical test have been conducted to evaluate the Exilis SP II performance, and results confirm that the device performs as intended and in a similar manner compared to the predicate. Thus, the Exilis XP II is substantially equivalent to the predicate devices.

Comparison with the Predicate Device

Device Name	Exilis XP II	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	Current Submission	K143040
Product Code **Regulation**	General & Plastic Surgery 21 CFR 878.4400 • PBX, Electrosurgical, Cutting & Coagulation & Accessories	General & Plastic Surgery 21 CFR 878.4400 • PBX, Massager, Vacuum, Radio Frequency Induced Heat
Indications for Use	The Exilis XP II 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 Exilis XP II massage device is intended to provide a temporary reduction in the appearance of cellulite.	The Exilis XP 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 Exilis XP massage device is intended to provide a temporary reduction in the appearance of cellulite.

Device Name	Exilis XP II	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	Current Submission	K143040
Device Technologies	Application of the heat to the tissue via RF energy. Massaging of body parts with massage device.	Application of the heat to the tissue via RF energy. Massaging of body parts with massage device.
Electrical Protection	Class II, BF	Class II, BF
Color Touch Screen	8.4" (21.5cm)/640x480 pixel	8.4" (21.5cm)/640x480 pixel
Exchangeable Applicator Tips Available	Yes	No
Maximum Output Power	120 W	120 W
Effective Treatment Temperature	40 - 45 °C	40 - 45 °C
Modes of Operation	Monopolar	Monopolar
Output Frequency	3.25 MHz	3.25 MHz
Energy Source	100 - 240 VAC, max 4A, 50-60 Hz	100 - 240 VAC, max 4A, 50-60 Hz
Dimensions (W x H x D)	16" x 10.6" x 11.9" (41 cm x 22 cm x 18 cm)	16" x 10.6" x 11.9" (41 cm x 22 cm x 18 cm)
Weight	16 lb (7.3 kg)	16 lb (7.3 kg)

Substantial Equivalence

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

Conclusion

Based on the aforementioned information, the changes in Exilis XP II do not raise any new questions of safety and effectivity and the device is substantially equivalent to the identified predicate device.