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 15, 2015

BTL Industries Incorporated
Jan Zarsky
Executive Vice President
47 Loring Drive
Framingham, Massachusetts 01702

Re: K143040
Trade/Device Name: Exilis XP
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: December 29, 2014
Received: December 31, 2014

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 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" (21CFR 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,

David Krause -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)*

K143040

Device Name

Exilis XP

Indications for Use *(Describe)*

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.

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.

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Section 5 – 510(k) Summary

General Information

Sponsor: BTL Industries, Inc.
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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: 14 September 2014

Device Names

Trade/Proprietary Name:	Exilis XP
Primary Classification Name:	Electrosurgical cutting and coagulation and accessories
Classification Regulation:	878.4400
Product Code:	PBX

Legally Marketed Predicate Devices

The Exilis XP 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:

- PelleFirm System (K132949)

Product Description

The Exilis XP is a state-of-the-art radiofrequency device, with integrated massaging heads, 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.

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 consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic energy generator
- user interface with 8.4” color touch screen
- handpiece for an application of radiofrequency
- two massage heads

Indications for Use

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.

Non-clinical Testing

The Exilis XP device has been thoroughly evaluated for electrical safety. The Exilis XP 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

ISO 60601-1	General requirements for safety
ISO 60601-1-2	Electromagnetic compatibility–Requirements and Tests
ISO 60601-2-2	Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories
ISO 60601-1-6	Usability
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 system is not based upon clinical performance testing. The device safety and efficacy was demonstrated by comparison of technical characteristics between the Exilis XP and compared to the predicate device.

Comparison with the Predicate Device

Device Name	Exilis XP	PelleFirm
Manufacturer	BTL Industries, Inc.	Ellman International, Inc.
510(k) Number	Current Submission	K132949
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 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.	The PelleFirm 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 PelleFirm 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 device.	Application of the heat to the tissue via RF energy. Massaging of body parts with massage device.
Electrical Protection	Class II, BF	Class I, BF
Color Touch Screen	8.4" (21.5cm)/640x480 pixel	N/A
RF Tip Diameter	1.8cm	2.3cm
Maximum Output Power	120W	120W

Device Name	Exilis XP	PelleFirm
Manufacturer	BTL Industries, Inc.	Ellman International, Inc.
510(k) Number	Current Submission	K132949
Effective Treatment Temperature	40 - 45 ℃	40 - 45 ℃
Modes of Operation	Monopolar	Monopolar
Output Frequency	3.25MHz	4 MHz
Massage Attachment Material	White Plastic material	White Plastic material
Massage Attachment 1	Diameter 80 mm, Massage ball diameter 19mm, Massage ball number: 5	Diameter 80 mm, Massage ball diameter 19, Massage ball number: 5
Massage Attachment 2	Diameter 52mm, Massage ball diameter 12mm Massage ball number: 5	Diameter 52mm, Massage ball diameter 12mm, Massage ball number: 5
Energy Source	100 - 240 VAC, max 4A, 50-60 Hz	110 - 240 V, 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)	9.5" x 7.1" x 16.5" (24 cm x 18 cm x 42 cm)
Weight	16 lb (7.3 kg)	26 lb (11.8 kg)

Substantial Equivalence

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

Conclusion

Based on the aforementioned information, the Exilis XP is safe and effective and substantially equivalent to the identified predicate device.