



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

September 16, 2015

Re: K150720

Trade/Device Name: XP3000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 18, 2015
Received: August 20, 2015

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,

Joshua C. Nipper -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

Indications for Use

510(k) Number (if known)

K150720

Device Name

XP3000

Indications for Use (Describe)

The XP3000 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 XP3000 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.

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
PRASStaff@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."



Section 5 – 510(k) Summary

General Information

Sponsor: BTL Industries, Inc.
47 Loring Drive
Framingham, MA 01702
Tel: [+1-866-285-1656](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](tel:+1-866-285-1656)
Fax: +1-888-499-2502

Contact Person: Jan Zarsky
BTL Industries, Inc.
Executive VP
zarsky@btlnet.com

Summary Preparation
Date: 12 February 2015

Device Names

Trade/Proprietary Name: XP3000

Primary Classification Name: Massager, Vacuum, Radio Frequency Induced Heat

Classification Regulation: 878.4400

Product Code: PBX

Legally Marketed Predicate Devices

The XP3000 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

The XP3000 is a state-of-the-art radiofrequency device with massage attachments 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 handpieces are 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 displays show the selected treatment parameters.

Any therapeutic parameter can be set easily by simple use of the touch-screen buttons. During the entire therapy time the device informs you about the therapeutic method, the type of the therapy applied, the set power, and other necessary data.

The XP3000 consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic energy generator
- user interface with 8.4" color touch screen
- handpiece XP (215/3)
- two massage attachments for the XP handpiece
- large handpiece (215/1) with integrated massage part
- large handpiece (215/1)

Indications for Use

The XP3000 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 XP3000 massage device is intended to provide a temporary reduction in the appearance of cellulite.

Non-clinical Testing

The XP3000 device has been thoroughly evaluated for electrical safety. The XP3000 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 XP3000 is based on clinical performance testing. The aim of the performance test was to prove that XP3000 device reaches the effective treatment temperature and maintain it for required time.

Comparison with the Predicate Device

Device Name	XP3000	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	Current Submission	K143040
Product Code	<u>General & Plastic Surgery</u> 21 CFR 878.4400	<u>General & Plastic Surgery</u> 21 CFR 878.4400
Regulation	• PBX, Massager, Vacuum, Radio Frequency Induced Heat	• PBX, Massager, Vacuum, Radio Frequency Induced Heat
Indications for Use	The XP3000 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 XP3000 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 Technologies	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment.	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)/640×480 pixel	8.4" (215mm)/640×480 pixel
RF Tip Diameter XP Handpiece (215/3)	18mm	18mm
RF Tip Diameter Large	21.4mm	N/A



Device Name	XP3000	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	Current Submission	K143040
Handpiece with Integrated Massage Part (215/1)		
RF Tip Diameter Large Handpiece without Integrated Massage Part (215/1)	21.4mm	N/A
Maximum Output Power	Handpiece 215/3 – 120W Handpiece 215/1 – 170W	Handpiece 215/3 – 120W Handpiece 215/1 – N/A
Energy Density	0.473 W/mm ²	0.472 W/mm ²
Effective Treatment Temperature	40 - 45 °C	40 - 45 °C
Large Handpiece (215/1) Cooling	YES	N/A
Modes of Operation	Monopolar	Monopolar
Output Frequency	3.25MHz ± 50kHz	3.25MHz ± 50kHz
Massage Attachment Material	Grey Plastic material	Grey Plastic material
Massage Attachment 1 (XP Handpiece)	Diameter 80 mm, Massage ball diameter 19mm, Massage ball number: 5	Diameter 80 mm, Massage ball diameter 19mm, Massage ball number: 5
Massage Attachment 2 (XP Handpiece)	Diameter 52mm, Massage ball diameter 12mm Massage ball number: 5	Diameter 52mm, Massage ball diameter 12mm Massage ball number: 5
Massage Part (Large Handpiece)	Diameter 80mm, Massage ball diameter 19mm, Massage ball number: 5	N/A



Device Name	XP3000	Exilis XP
Manufacturer	BTL Industries, Inc.	BTL Industries, Inc.
510(k) Number	Current Submission	K143040
Energy Source	100 - 240 VAC, max 4A, 50-60 Hz	110 - 240 V, max 4A, 50-60 Hz
Dimensions (W x H x D)	600 × 1000 × 600mm (24" × 39" × 24")	406 × 270 × 302mm (15.98" × 10.63" × 11.87")
Weight	66 lb (30 kg)	16 lb (7.3 kg)

Substantial Equivalence

Based upon the intended use and technical information provided in this pre-market notification, the XP3000 device has been shown to be substantially equivalent to currently marketed predicate device.

Conclusion

Based on the aforementioned information, the XP3000 is safe and effective and substantially equivalent to the identified predicate device.