DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 11, 2015

BTL Industries Incorporated
% Dr. Michail Pankratov
MMP Medical Associates, LLC
16 Appleton Street
Waltham, Massachusetts 02453

Re: K143559
Trade/Device Name: XP1000 RF
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 6, 2015
Received: May 7, 2015

Dear Dr. Pankratov:

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,

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)*
K143559

Device Name
XP1000 RF

Indications for Use *(Describe)*
The XP1000 RF device is indicated for temporary reduction in circumference of the abdomen.

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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K143559

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: Michail Pankratov
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Summary Preparation Date: June 3, 2015

Device Names

Trade/Proprietary Name: XP1000 RF

Primary Classification Name: Electrosurgical Cutting and Coagulation Device & Accessories

Classification Regulation: 878.4400

Product Code: GEI

Legally Marketed Predicate Devices

The XP1000 RF system is a state-of-the-art high-frequency energy device with accessory, and is substantially equivalent to the current product that is already cleared for USA distribution under the following 510(k) Premarket Notification number:

- Transcend System (K120510)

Product Description

The XP1000 RF system is designed for temporary reduction in circumference of the abdomen by means of high-frequency electromagnetic field.

The multi-jointed arm firmly supports the applicator during treatment. Large knobs lock and unlock the joints to make positioning the applicators to the patient quick, easy and secure.

The control unit consists of the control system and the electronic system. The control system contains the main microcomputer and software for control of the entire equipment; the electronic system contains the complete electronics for electromagnetic field generation. Easy-to-use color touch screen allows for maximum operator comfort. A large control knob is provided to increase and decrease output power.

The XP1000 RF system is placed in a specially designed cart, the shape of which provides maximum operator comfort and easy movement of the device in the office.

The XP1000 RF consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic energy generator
- user interface with 8.4” color touch screen
- applicator on a multi-jointed arm

Indications for Use

The XP1000 RF is indicated for temporary reduction in circumference of the abdomen.

Non-clinical Testing

The XP1000 RF device has been thoroughly evaluated for electrical safety and performance. The XP1000 RF 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 60601-1-6 Usability
IEC 60601-2-2 Particular requirements for basic safety and performance of high frequency surgical equipment
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 device was clinically tested for reduction of abdominal circumference by disruption of adipocyte cells.

Sixty subjects, ranging from 19 to 53 years of age, were enrolled in the double blinded study and divided into 2 groups: 40 to the XP1000 RF Treatment Group and 20 to the Sham (Placebo) Group. All subjects but one finished the study.

The Treatment Group subjects have met the primary efficacy outcome measure by achieving ≥3 cm waist circumferential reduction in more than 80% of subjects. The mean circumferential reduction was ≥1 cm than the mean circumferential reduction of the Placebo Group at the 30-day Follow Up evaluation point.

Waist circumference changes (Baseline data vs the 30-day and 90-day Follow Up data) between the XP1000 RF Treatment subjects and the Placebo Group were statistically highly significant.

The secondary objective was absence of adverse events (AE) associated with the treatment procedure. The secondary objective was met with no adverse events recorded.

The clinical study supports the effectiveness of the device for temporary reduction of abdominal circumference.

The efficacy of XP1000 RF was not established at power level settings below maximum power of 200 points. The device is indicated for patients 22 years or older because its safety and effectiveness have not been established in pediatric patients or patients younger than 22 years.

Comparison with the Predicate Device

510(k) number	**K143559**	**K120510**
Device name	XP1000 RF	Transcend System
Company name	BTL Industries, Inc.	Syneron Medical Ltd.
Product Code Regulation	General & Plastic Surgery 21 CFR 878.4400 -GEI, Electrosurgical Cutting and Coagulation Device &	General & Plastic Surgery 21 CFR 878.4400 -GEI, Electrosurgical Cutting and Coagulation Device &

510(k) number **Device name** **Company name**	**K143559** XP1000 RF BTL Industries, Inc.	**K120510** Transcend System Syneron Medical Ltd.
	Accessories.	Accessories.
Indications for Use	The XP1000 RF is indicated for temporary reduction in circumference of the abdomen.	The Transcend is indicated for temporary reduction in circumference of the abdomen.
Deep tissue Heating Electromagnetic Energy	Radiofrequency	Radiofrequency + InfraRed
Vacuum	No	Yes
Electrical Protection	Class II, BF	Class I, BF
Unit Construction	Constructed of materials that conform with safety standards and requirements.	Constructed of materials that conform with safety standards and requirements.
Interface	Touch-screen user applied interface to program and set the controls for the patient application; there is an applicator utilized to deliver the treatment.	Touch-screen user applied interface to program and set the controls for the patient application; there is a hand-piece utilized to deliver the treatment.
Color Touch Screen	8.4" (21.5cm)/640x480 pixel	10.1" (25.7 cm)
Modes Of Operation	Bipolar	Bipolar

510(k) number	K143559	K120510
Device name	XP1000 RF	Transcend System
Company name	BTL Industries, Inc.	Syneron Medical Ltd.
Nominal Operating Power	Max: 200W RF	Max: 151.7W (150W RF, 1.7 or 3.3W IR)
RF Carrier Frequency	27.12 MHz (±400kHz)	1 MHz
Operating Temperature	10°C to 30°C	15°C to 30°C
Operating Humidity	30% - 75%	Up to 80%
Skin Temperature Monitoring	Based on patient's feedback. External IR thermometer.	Based on patient's feedback. Built-in IR thermometer.
Treatment Temperature Range	40°C – 45°C	40°C – 45°C
Cooling	Not Available	Not Available
Cooling Mechanism	Not Available	Not Available
Applicator Holder Availability	YES	YES
Waveform	Sinusoid	Sinusoid
Applicator Effective Area	20,106 mm^2	1,250 mm^2 750 mm^2 130 mm^2
Treatment Time	Up to 45 min. per treated area (waist)	Up to 45 min. per treated area (waist)
Total Energy Density (fluence)	3.6 - 27 J/mm^2	3.6 J/mm^2 6.0 J/mm^2 34.6 J/mm^2
Material of the Generator Case	Plastic/metal	Plastic/metal
Dual Dispersive Patch Electrode Grounding	NO	NO
Patch Electrode Contact Quality Monitoring	YES	N/A

510(k) number	**K143559**	**K120510**
Device name	XP1000 RF	Transcend System
Company name	BTL Industries, Inc.	Syneron Medical Ltd.
RF Energy Emission Indicator	YES; Information displayed on the screen of the unit	YES
Applicator Weight	3.9 lbs (1760 g)	2.2 lbs (1 kg)
Energy Source	100 – 240 VAC, max 5A, 50 – 60Hz	110 – 230 VAC, max 5A, 50Hz
External Exchangeable Fuse	2 × T4A / 250V, tube fuse 5 × 20 mm	Available
System Dimensions	22" × 39" × 22" (56 cm x 98 cm x 56 cm)	15" × 19" × 51.8" (132 cm × 49 cm × 38 cm)
System Weight	83 lbs (38 kg)	44.1 lbs (20 kg)

Substantial Equivalence

Based upon the intended use and technical information provided in this pre-market notification, the XP1000 RF device has been shown to be substantially equivalent to currently marketed predicate device.

Conclusion

Based on the aforementioned information, the XP1000 RF is safe and effective and substantially equivalent to the identified predicate device.