



Food and Drug Administration  
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July 20, 2016

BTL Industries, Inc.  
c/o Michail M. Pankratov, Principal  
MMP Medical Associates LLC  
16 Appleton St., Waltham, MA 02453

Re: K152731

Trade/Device Name: XP1100 RF

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical, Cutting & Coagulation Device & Accessories

Regulatory Class: Class II

Product Code: GEI

Dated: June 17, 2016

Received: June 24, 2016

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

**Christopher J. Ronk -A**

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)  
K152731

Device Name  
XP1100 RF

Indications for Use (Describe)

The XP1100 RF is indicated for temporary reduction in circumference of the abdomen and thighs.

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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## K152731 510(k) Summary

### General Information

Sponsor: BTL Industries, Inc.  
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Applicant: BTL Industries, Inc.  
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Summary Preparation  
Date: 7 September 2015

### Device Names

Trade/Proprietary Name: XP1100 RF

Primary Classification Name: Electrosurgical Cutting and Coagulation Device & Accessories

Classification Regulation: 878.4400

Product Code: GEI

### Legally Marketed Predicate Devices

The XP1100 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:

- XP1000 RF (K143559)

### Product Description

The XP1100 RF system is designed for temporary reduction in circumference of the abdomen and thighs 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 XP1100 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 XP1100 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 XP1100 RF is indicated for temporary reduction in circumference of the abdomen and thighs.

## Non-clinical Testing

The XP1100 RF device has been thoroughly evaluated for electrical safety and performance. The XP1100 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	General requirements for basic safety and essential performance of high frequency surgical 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 XP1100 RF device was clinically tested for reduction of thighs circumference by disruption of adipocyte cells. Forty subjects (28 women, 12 men), ranging from 23 to 54 years of age, skin type in range from II to IV, race/ethnicity white, were enrolled in the open label study. Treated subjects received 4 treatment sessions (30 minutes per each leg) delivered once a week over a 4-week period.

The subjects have met the primary efficacy outcome measure by achieving  $\geq 1$  cm thighs circumferential reduction in more than 80 % of subjects. Thighs circumference change (Baseline data vs. the 30-day and 90 day-Follow Up) was statistically highly significant.

The secondary objective was absence of adverse events and subjects satisfaction with the therapy. The secondary objective was met with no adverse events recorded and more than 80% of treated subjects reported satisfaction with the therapy at 30-day and 90 day-Follow Up.

More than 80% of treated subjects reported aesthetic appearance improvement at 30 day-Follow Up and more than 76% of treated subjects reported aesthetic appearance improvement at 90 day-Follow Up.

The statistical methods used: Two Sample t-Test: Unequal Variances and t-Test: Paired Two Sample For Means. The clinical study of XP1100 RF device supports the effectiveness of the device for temporary reduction of thighs circumference.

## Comparison with the Predicate Device

<b>510(k) number</b>	<b>K152731</b>	<b>K143559</b>
<b>Device name</b>		XP1000 RF
<b>Company name</b>	XP1100 RF BTL Industries, Inc.	BTL Industries, Inc.
<b>Product Code Regulation</b>	<u>General &amp; Plastic Surgery</u> 21 CFR 878.4400 -GEI, Electrosurgical Cutting and Coagulation Device & Accessories.	<u>General &amp; Plastic Surgery</u> 21 CFR 878.4400 -GEI, Electrosurgical Cutting and Coagulation Device & Accessories.
<b>Intended Use</b>	Non-invasive radiofrequency body shaping device.	Non-invasive radiofrequency body shaping device.
<b>Indications for Use</b>	The XP1100 RF is indicated for temporary reduction in circumference of the abdomen and thighs.	The XP1000 RF is indicated for temporary reduction in circumference of the abdomen.
<b>Deep tissue Heating Electromagnetic Energy</b>	Radiofrequency	Radiofrequency



<b>510(k) number</b>	<b>K152731</b>	<b>K143559</b>
<b>Device name</b>		XP1000 RF
<b>Company name</b>	XP1100 RF BTL Industries, Inc.	BTL Industries, Inc.
<b>Electrical Protection</b>	Class II, BF	Class II, BF
<b>Unit Construction</b>	Constructed of materials that conform with safety standards and requirements.	Constructed of materials that conform with safety standards and requirements.
<b>Interface</b>	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 an applicator utilized to deliver the treatment.
<b>Color Touch Screen</b>	8.4 in 21.5 cm 640×480 pixel	8.4 in 21.5 cm 640×480 pixel
<b>Modes Of Operation</b>	Bipolar	Bipolar
<b>Nominal Operating Power</b>	Max: 200 W RF	Max: 200 W RF
<b>RF Carrier Frequency</b>	27.12 MHz (±400 kHz)	27.12 MHz (±400 kHz)
<b>Operating Temperature</b>	10–30 °C	10–30 °C
<b>Operating Humidity</b>	30–75 %	30–75 %
<b>Skin Temperature Monitoring</b>	Based on patient's feedback. External IR thermometer.	Based on patient's feedback. External IR thermometer.
<b>Treatment Temperature Range</b>	40–45 °C	40–45 °C
<b>Applicator Holder Availability</b>	YES	YES
<b>Waveform</b>	Sinusoid	Sinusoid
<b>Applicator Models</b>	AB, EX	AB
<b>Applicators Effective Area</b>	AB: 201.06 cm <sup>2</sup> EX: 320.00 cm <sup>2</sup>	AB: 201.06 cm <sup>2</sup>



<b>510(k) number</b>	<b>K152731</b>	<b>K143559</b>
<b>Device name</b>		XP1000 RF
<b>Company name</b>	XP1100 RF BTL Industries, Inc.	BTL Industries, Inc.
<b>Treatment Time</b>	Up to 45 min using AB applicator, up to 30 min using EX applicator	Up to 45 min
<b>Total Energy Density</b>	AB: 0.994 W/cm <sup>2</sup> EX: 0.625 W/cm <sup>2</sup>	AB: 0.994 W/cm <sup>2</sup>
<b>Material of the Generator Case</b>	Plastic/metal	Plastic/metal
<b>RF Energy Emission Indicator</b>	YES; Information displayed on the screen of the unit	YES; Information displayed on the screen of the unit
<b>AB Applicator Weight</b>	3.9 lbs (1760 g)	3.9 lbs (1760 g)
<b>EX Applicator Weight</b>	2.8 lbs (1260 g)	n/a
<b>AB Applicator Dimensions</b>	686×192×105 mm (27×7.6×4.1 in)	686×192×105 mm (27×7.6×4.1 in)
<b>EX Applicator Dimensions</b>	732×287×124 mm (28×11,3×4,8 in)	n/a
<b>Energy Source</b>	100–240 VAC, max 5 A, 50–60 Hz	100–240 VAC, max 5 A, 50–60 Hz
<b>External Exchangeable Fuse</b>	T6.3 AL / 250 V, tube safety fuse 5×20 mm (for supply voltage ~ 100 V to 120 V)	T6.3 AL / 250 V, tube safety fuse 5×20 mm (for supply voltage ~ 100 V to 120 V)
<b>System Dimensions</b>	560×980×560 mm (22×39×22 in)	560×980×560 mm (22×39×22 in)
<b>System Weight</b>	84 lbs (38 kg)	84 lbs (38 kg)

### Substantial Equivalence

Based upon the intended use and technical information provided in this pre-market notification, the XP1100 RF device has been shown to be substantially equivalent to currently marketed predicate device.

### Conclusion

Based on the aforementioned information, the XP1100 RF is substantially equivalent to the identified predicate device.