DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 10, 2015

BTL Industries Incorporated
Mr. Jan Zarsky
Director
47 Loring Drive
Framingham, Massachusetts 01702

Re: K143109
Trade/Device Name: XP300
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, Cutting & Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 4, 2015
Received: February 9, 2015

Dear Mr. Zarsky:

This letter corrects our substantially equivalent letter of March 6, 2015.

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 8, 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)*

K143109

Device Name
XP300

Indications for Use *(Describe)*

The XP300 device is indicated for the primary treatment of dermatological procedures for non-invasive treatment of periorbital wrinkles and rhytids.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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510(k) Summary

for

XP300

1. Submission Sponsor

BTL Industries,
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MA, 01702
USA
Phone: 866.285.1656
Fax: 866.499.2502
Contact: Jan Zarsky, Director

2. Submission Correspondent

Mr. Jan Zarsky
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47 Loring Drive
Framington, MA 01702
USA
Email: zarsky@btlnet.com

3. Date Prepared

January 15, 2015

4. Device Identification

Trade/Proprietary Name:	XP300
Common/Usual Name:	Electrosurgical, cutting & coagulation & accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Trade/Proprietary Name:	XP200
Common/Usual Name:	Electrosurgical, cutting & coagulation & accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

6. Device Description

The XP300 device is indicated for the primary treatment of dermatologic procedures for noninvasive treatment of periorbital wrinkles and rhytids. The XP300 system is a state-of-the-art device to apply therapy by a non-invasive method of high-frequency field.

The control unit of the device is fitted with a color touch screen, which significantly facilitates the use of the device. The design of the device enables the operator to see the on-screen information from various angles during the procedure. In addition, the brightness of the screen can be set to match the lighting in the room. The on-screen information will guide you through the entire therapy by means of easy setting of parameters using touch-screen buttons and knobs/keys on the device.

For easier control, the applicator is equipped with buttons, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters. The XP300 device incorporates the ultrasonic feature for added patient comfort.

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 XP300 consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic generator and ultrasonic element
- user interface with 8.4” colour touch screen
- applicator with colour screen and control buttons

The main change between this device and the predicate is the inclusion of the Ultrasonic convenience function which is intended to improve patient’s comfort during the procedure

7. Indication for Use Statement

The XP300 is indicated for the primary treatment of dermatological procedure for non-invasive treatment of periorbital wrinkles and rhytids.

8. Substantial Equivalence Discussion

The following table compares the XP300 to the predicate device, XP200, with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	BTL Industries, Inc.	BLT Industries, Inc.	SIGNIFICANT DIFFERENCES
Trade Name	XP300	XP200	n/a
510(k) Number	Unknown	K122966	n/a
Product Code	GEI	GEI	No difference
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	No difference
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	No difference
Intended Use	Application of heat to the tissue w/RF energy	Application of heat to the tissue w/RF energy	No difference
Indications for Use	The XP300 is indicated for the primary treatment of dermatological procedure for non-invasive treatment of periorbital wrinkles and rhytids.	The XP200 is indicated for the primary treatment of dermatological procedure for non-invasive treatment of periorbital wrinkles and rhytids.	No difference
Material	The unit is constructed of material that conform with safety standards and requirements.	The unit is constructed of material that conform with safety standards and requirements.	No difference
Sterile	No	No	No difference
Single-Use	No	No	No difference
Interface	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.	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.	No difference.
The ultrasonic convenience Function	Yes	No	No significant difference. The change is being introduced to improve patient's comfort during the application. There is no change to the principle of operation.

Manufacturer	BTL Industries, Inc.	BLT Industries, Inc.	SIGNIFICANT DIFFERENCES
Trade Name	XP300	XP200	n/a
Color Touch Screen	8.4" (2.15 cm)/640x480 pixels	8.4" (2.15 cm)/640x480 pixels	No difference
Energy Type	Radiofrequency	Radiofrequency	No difference
Modes of Operation	Monopolar	Monopolar	No difference
Nominal Operating power	120 W	120 W	No difference
Operating temperature	18°C to 30°C	18°C to 30°C	No difference
Operating Humidity	60%-75%	60%-75%	No difference
Temperature Treatment Range	39°C to 42°C	39°C to 42°C	No difference
Power Level Adjustable via Applicator	Yes	Yes	No difference
Patch Electrode Contact Quality Monitoring	Yes	Yes	No difference
RF Energy Emission Indicator	Yes; Information displayed on the screen of the applicator and on the main screen of the unit.	Yes; Information displayed on the screen of the applicator and on the main screen of the unit.	No difference
Applicator Dimensions	4.25" x 2.6" x 7" (11cm x 7cm x18cm)	4.25" x 2.6" x 7" (11cm x 7cm x18cm)	No difference
Complies with ISO 10993-1	Yes	Yes	No difference
Electrical Safety Testing Passed	Class II, BF	Class II, BF	No difference
Energy Source	100-240 VAC, max 4A, 50-60 Hz	100-240 VAC, max 4A, 50-60 Hz	No difference
System Dimensions	16" X 10.6" x 11.9" (41cm x 22cm x 18cm)	16" X 10.6" x 11.9" (41cm x 22cm x 18cm)	No difference
System Weight	16lb (7.3kg)	16lb (7.3kg)	No difference

9. Non-Clinical Performance Data

This Special 510(k) proposes a modification to the applicator by incorporating an ultrasonic element to improve patient's comfort during the application.

This proposed change does not impact the indications for use, technology, principle of operation, patient contact materials, or packaging of the device. Testing has been performed on the modified applicator to demonstrate that treatment heads applied to the patient shall have a convenient patient contact surface temperature.

The change only applies to the applicator therefore XP300 continues to conform to the medical device safety standards applicable to both XP300 and XP200. The device has been evaluated to demonstrate electrical, electromagnetic and mechanical safety. Medical device software life cycle processes have been verified and validated as well as output and biocompatibility.

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

MedicalElectricalEquipment:
IEC 60601-1 General requirements for safety
IEC 60601-1-2 Collateral Standard: Electromagnetic compatibility – Requirements and Tests
IEC 60601-2-2 Particular requirements for the safety of high frequency surgical equipment
IEC 60601-1-6 General requirements for basic safety and essential performance Collateral standard: Usability

EMCRequirementsforMedicalEquipment:
IEC 61000-4-2; IEC 61000-4-3; IEC 61000-4-4; IEC 61000-4-5

BiologicalEvaluationforMedicalDevices:
ISO 10993-1; ISO 10993-5; ISO 10993-10

PerformanceTesting:
- Frequency Accuracy and Carrier Wave Form
- Carrier Wave Nominal Output Power
- Power Fluency
- Tissue Heating:

The performance testing confirmed safety of simultaneous application of radiofrequency and ultrasound energy.

The XP300 meets all the requirements for overall design, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The XP300 complies with the applicable voluntary standards for biocompatibility.

10. Clinical Performance Data

    There was no clinical testing required to support the XP 300 medical device as the indications for use are equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Biocompatibility and Sterilization/Shelf-life

    The change does not impact the biological safety of the device. The XP200 device biocompatibility was tested according to the ISO 10993-1; ISO 10993-5; ISO 10993-10.

    There are no changes in the product life and shelf life compared to that of XP200 device. The device shelf life is 5 years. The product life is 5 years.

    The device is not intended to be sterile and is not intended to be sterilized by the user.

12. Statement of Substantial Equivalence

    It has been shown in this 510(k) submission that the differences between the XP300 and the predicate device do not raise any questions regarding its safety and effectiveness. The XP300, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device; XP200.