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

April 8, 2015

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

Re: K150051
Trade/Device Name: Exilite
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: January 6, 2015
Received: January 12, 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,

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)*
K150051

Device Name
Exilite

Indications for Use *(Describe)*
Exilite system (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in reduction of pigmented lesions, acne therapy, freckle, vascular lesions, facial blemish removal, and permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.

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.

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Section 5 – 510(k) Summary

General Information

Sponsor:	BTL Industries, Inc. 47 Loring Drive Framingham, MA 01702 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 Fax: +1-888-499-2502
Contact Person:	Jan Zarsky BTL Industries, Inc. Executive VP zarsky@btlnet.com
Summary Preparation Date:	6 January 2015

Device Names

Trade/Proprietary Name:	Exilite
Common Name:	Intense Pulsed Light (IPL)
Primary Classification Name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Classification Regulation:	878.4810
Product Code:	ONF

Legally Marketed Predicate Devices

The Exilite system is an Intense Pulsed Light (IPL) system, and is substantially equivalent to the current product which is already cleared for USA distribution under the following 510(k) Premarket Notification number:

- Intense Pulsed Light (IPL) Systems – Beijing KES Biology Technology Co., Ltd (K122995)

Product Description

The Exilite device is indicated for the primary treatment of dermatologic deficiencies. It is Intense Pulsed Light System which uses a wide spectrum of light from 480 to 1200nm (yellow, green, red and infrared light).

The control unit of the device is fitted with a color touch screen, which significantly facilitates the use of the device. 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 handpiece is equipped with trigger button, enabling to start the application instead of footswitch.

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 chosen therapy and applied filter, the set fluence and other necessary data.

The Exilite consists of the following main components:

- control unit
- user interface with 8.4” color touch screen
- handpiece with cooling sapphire crystal and trigger button

Indications for Use

Exilite system (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in reduction of pigmented lesions, acne therapy, freckle, vascular lesions, facial blemish removal and permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.

Non-clinical Testing

The Exilite device has been thoroughly evaluated for electrical safety. The Exilite 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

<u>Medical Electrical Equipment</u>

ISO 60601-1	General requirements for safety
ISO 60601-1-2	Electromagnetic compatibility–Requirements and Tests
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 Exilite system is not based upon clinical performance testing. The device safety and efficacy was demonstrated by comparison of technical characteristics between the Exilite as compared to the predicate devices.

Comparison with the Predicate Device

Device name	Exilite	Intense Pulsed light (IPL) Systems
Manufacturer	BTL Industries Ltd.	Beijing KES Biology Technology Co., Ltd.
510(k) number	Current submission	K122995
Light Source	Intense Pulsed Light	Intense Pulsed Light
Emitted by	Flash lamp	Flash lamp
Operating Conditions	Ambient temperature +15 °C to +30 °C	N/A
	Relative humidity 30% to 75%	N/A
	Atmospheric pressure 700hPa to 1060hPa	N/A
	Position on castors	N/A
Operation	Touch screen	Touch screen
Wavelength	480 – 1200 nm	430 – 1200 nm
Deliver System	Sapphire	Sapphire
Indications for Use	Exilite system (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical and aesthetic applications in reduction of pigmented lesions, acne therapy, freckle, vascular lesions, facial blemish removal and permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.	The Intense Pulsed Light (IPL) Systems (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in permanent hair removal, skin rejuvenation, reduction of pigmented lesions, acne therapy, freckle, vascular lesions and facial blemish removal.

Device name	Exilite	Intense Pulsed light (IPL) Systems
Manufacturer	BTL Industries Ltd.	Beijing KES Biology Technology Co., Ltd.
510(k) number	Current submission	K122995
Electrical Protection	Class II, BF	Class II, BF
Maximal Fluence	10-60J/cm^2	10-60J/cm^2
Spot Size	11x40mm	12x33mm 15x50mm 15x35mm
Pulse Delay	1-50ms	5-50 ms
Pulse Duration	1-20ms	3-20ms
Pulse Type	Single, multiple	Single, multiple
Electrical Requirements	100-240 V, 50-60 Hz	220V±20V, 50Hz or 110V±20V, 60Hz, 20A
Weight	45.55kg	23kg
Dimensions W x H x D	System console - 580 x 980 x 580 mm	440 x 500 x 350 mm
Cooling	Sapphire	Sapphire
Cooling Method	Continuous contact cooling	Continuous contact cooling
Device clasification	II: 21 CFR 878.4810	II: 21 CFR 878.4810
Product Code	ONF	ONF
Standards	IEC 60601-1, IEC 60601-1-2, ISO 10993-5, ISO 10993-10, ISI 14971, IEC 62304	IEC 60601-1, IEC 60601-1-2

Substantial Equivalence

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

Conclusion

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