APR 1 1 2013

Attachment 5
510(K) Summary as required by section 807.92(c).
MultiLaser System

K123777

This 510(K) Summary of safety and effectiveness for the MultiLaser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	UltraLight Laser Technologies, LLC
Address:	UltraLight Laser Technologies LLC 105 Citation Court Birmingham, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone: Fax: Email:	1-205-356-1172 1-205-356-1171 ssmed@bellsouth.net
Preparation Date:	November 30, 2012
Device Trade Name:	MultiLaser System
Common Name:	Laser
Classification Name:	Instrument, Surgical, Powered, laser GEX, 21 CFR 878.4810 Powered light based non-laser surgical instrument with thermal effect ONF, 21 CFR 878.4810
Classification	Class II
Legally Marketed Predicate Device(s):	TriPlex Laser System (K)110502 Apex Laser System (K)110304 Cheveux Laser System (K)100893
Description of the MultiLaser System:	The MultiLaser System consists of a console that houses the power supply, control electronics and user interface and four separate handpiece. The four handpieces consist of an Er:YAG laser handpiece, an Nd:YAG laser handpiece, a Diode laser handpiece and an IPL handpiece.
Intended use of the MultiLaser System	The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery). The Nd:YAG handpiece is indicated for: • At the 1064 nm wavelength - dark ink tattoo removal, removal of pigmented lesions and the removal or lightening of hair. • At the 532 nm wavelength - removal of red ink tattoos, treatment of vascular lesions including facial

and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains and most pigmented lesions (e.g. lentigies, ephildes)

The Diode laser is indicated for use on all skin types (Fitzpatrick Skin Types I-VI) including tanned skin for:

- Hair Removal
- Permanent hair reduction
- Treatment of vascular lesions
- Treatment of benign pigmented lesions
- Treatment of Leg Veins
- Treatment for pseudofolliculitis barbae

The IPL Handpiece is indicated for use in skin types I-IV according to the Fitzpatrick Scale for the following indications:

- Hair Removal (650nm filter)
- Permanent hair reduction (650nm filter)
- Treatment of vascular lesions (510nm filter)
- Treatment of benign pigmented lesions (510 nm filter)
- Mild to Moderate inflammatory acne (450nm filter)

Performance Data: None

Results of Clinical Study: None

Technical Specifications Comparison:

K123777

Nd:YAG Handpiece Specification

	UltraLight LLC Multi-Laser System	Sandstone Medical Technologies LLC TriPlex (K110502)
Energy	Up to 1000mj	Up to 1000mJ
Maximum Fluence	12J/cm2	12J/cm2
Wavelength	1064nm and 532nm	1064nm and 532nm
Spot Size	up to 5mm	up to 5mm
Pulse Width	10ns	10ns
Pulsewidth	Single pulse and variable . 0.06 sec - continuous	Single pulse and variable . 0.06 sec - continuous
Repetition Rate	1-5Hz	1-5Hz
Aiming Beam	HeNe	HeNe

Diode Laser Handpiece Specification

	UltraLight LLC Multi-Laser System	Sandstone Medical Technologies LLC Cheveux (K100893)
Light Source	Diode Array	Diode Array
Wavelength	810nm	810nm
Energy Density	Up to 100J/cm^2	Up to 100J/cm^2
Spot Size	14x 10 mm	14x 10 mm
Pulse Width	Up to 400ms	Up to 400ms
Beam Delivery System	Light Guide	Light Guide

Er:YAG Laser Handpiece Specification

	UltraLight LLC Multi-Laser System	Sandstone Medical Technologies LLC TriPlex (K110502)
Wavelength	2940nm	2940nm
Max Power	2.4 W	2.4 W
Max Fluence	8 J/cm2	8 J/cm2
Pulse Width	300 µs	300 µs
Repetition Rate	Up to 10 pulse per second	Up to 10 pulse per second
Spot Size	1.5mm, 3mm, 6mm, 9mm	1.5mm, 3mm, 6mm, 9mm

Intense Pulsed Light (IPL) Handpiece Specification

	UltraLight LLC Multi-Laser System	Sandstone Medical Technologies LLC Apex (K110304)
Light Source	Pulsed Incoherent Light	Pulsed Incoherent Light
Max Fluence	Up to 35J/cm^2	Up to 35J/cm^2
Wavelength	450 - 1200 nm	450 - 1200 nm
Spot Size	35 x 15 mm^2	35 x 15 mm^2
Pulse Width	Up to 200ms	Up to 200ms
Beam Delivery Stem	Light Guide	Light Guide

Conclusion: The MultiLaser System is substantially equivalent to other existing laser and IPL systems in commercial distribution for use in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

UltraLight Laser Technologies, LLC
% Mr. Mark Rohrer
105 Citation Court
Birmingham, Alabama 35209

April 11, 2013

Re: K123777
Trade/Device Name: MultiLaser System
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: GEX
Dated: February 21, 2013
Received: March 11, 2013

Dear Mr. Rohrer:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123777

Device Name: Multi-Laser Laser System

The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

The Nd:YAG handpiece is indicated for:

- At the 1064 nm wavelength - dark ink tattoo removal, removal of pigmented lesions and the removal or lightening of hair.
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Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123777

The IPL Handpiece is indicated for use in skin types I-IV according to the Fitzpatrick Scale for the following indications:

- Hair Removal (650nm filter)
- Permanent hair reduction (650nm filter)
- Treatment of vascular lesions (510nm filter)
- Treatment of benign pigmented lesions (510 nm filter)
- Mild to Moderate inflammatory acne (450nm filter)

Prescription Use ___xx___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123777