



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

June 29, 2016

Focus Medical LLC
Mr. John Lee
Owner
23 Francis J. Clarke Circle
Bethel, Connecticut 06801

Re: K152737

Trade/Device Name: Lite Touch

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: May 5, 2016

Received: May 23, 2016

Dear Mr. Lee:

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" (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 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 -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)

K152737

Device Name

Lite Touch™ Er YAG Laser Treatment System

Indications for Use (Describe)

Lite Touch™ Er YAG Laser Treatment System is intended for the vaporization, incision, excision, dissection, ablation and/or photocoagulation of soft tissue in the following surgical specialties:

- Dermatology
- Cosmetic surgery
- Plastic and general surgery
- Oral surgery
- Gynecology
- Otorhinolaryngology
- Podiatry

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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Traditional 510k Submission Lite Touch™ Er YAG Laser Treatment System

510k Summary (21 CFR 807.92c)

Submitter: Focus Medical

Address: 23 Frances J. Clarke Circle
Bethel, CT, USA
06801

Phone: 203-730-8885

Fax: 203-730-8851

Date Prepared: 11 January 2016

Name of Submission Device: Lite Touch™, previously cleared under K974460

Trade or Proprietary Name: Lite Touch™

Common/Usual Name: Lite Touch™ Er:YAG Laser Treatment System

Classification: Class II

Regulation: 21 CFR 878.4810

Product Code: GEX

Classification Name: Powered Laser Surgical Instrument

Review Panel: General and Plastic Surgery

Predicate Device: Asceplion MCL 31 Dermablade (K150140)

Traditional 510k Submission Lite Touch™ Er YAG Laser Treatment System

Device Description:

The Lite Touch™ is an Er:YAG Laser Treatment System intended for use in the vaporization, incision, excision, dissection, ablation and/or photocoagulation of soft tissue in the following surgical specialties: Dermatology; Cosmetic surgery; Plastic and general surgery; Oral surgery; Gynecology; Otorhinolaryngology; and Podiatry.

The Lite Touch™ was previously cleared under K974460 in October 1997. This submission contains an expansion of the previously cleared indications for use. The Lite Touch™ consists of a streamlined, maneuverable cabinet that contains the laser source, control system, power supply and internal cooling system. The laser beam has a light wavelength of 2940nm and is delivered through a counterbalanced articulated arm and hand piece. There is a two stage process of dissimilar actions required to activate the laser beam. The operation of the Lite Touch™ are completely under the physician's control.

Indications for Use:

Lite Touch™ Er YAG Laser Treatment System is intended for the vaporization, incision, excision, dissection, ablation and/or photocoagulation of soft tissue in the following surgical specialties:

- Dermatology
- Cosmetic surgery
- Plastic and general surgery
- Oral surgery
- Gynecology
- Otorhinolaryngology
- Podiatry

Traditional 510k Submission Lite Touch™ Er YAG Laser Treatment System

Technological Characteristics:

Performance Characteristic	Lite Touch™	MCL 31 Dermablate
510K	Not assigned	K150140
Manufacturer	Focus Medical LLC	Asclepion Laser Technologies
Power	24w	20w
Energy (pulse and super pulse)	35-3000 mJ	2500mj max
Length of Pulse	300-1000us	100-1000us
Frequency of Pulse	Up to 16 Hz	20 Hz
Spot size at target	4, 6, 8,10 mm	1 – 12mm
Wavelength	2940 nm	2940 nm
Output mode	Pulsed	Pulsed
Beam delivery	Articulated Arm	Articulated Arm
Aiming Beam	635 nm	650nm
Laser medium	Flashlamp pumped solid state Er:YAG rod	Flashlamp pumped solid state Er:YAG rod
Cooling methods	Water/air heat exchanger	Water/air heat exchanger
Display/User Interface	Graphic user interface touchscreen	Graphic user interface touchscreen
Power calibration	Internal	Internal

The subject and predicate device K150140 use similar technology, and differences between the subject and predicate device do not raise any new types of questions regarding safety or effectiveness for the subject device's intended use.

Testing Performance:

The Lite Touch™ device for this 510(k) submission is fundamentally unchanged from the device that was cleared under K974460. The Lite Touch™ is in compliance with the requirements of 21 CFR 1040.10 - Performance Standards for light-Emitting Products, Laser products, and with 21 CFR 1040.11 - Performance Standards for Light-Emitting Products, Specific purpose laser products. The device has been tested for conformance to IEC 60601-1 Ed.3.0: 2005 + Corr 1. 2006 + Corr 2. 2007; EN 60601-1 :2006/AC: 2010 Medical electrical equipment. Part 1 General requirements for basic safety and essential performance, IEC 60601-1-2 2007, EN 60601-1-2: 2007; EN 60601-1-2 2007/AC 2010 Medical electrical equipment. Part 1-2 General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility - Requirements and tests; IEC 60601-2-22 2007, EN 60601-2-22 2013 Medical electrical equipment - Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment; IEC 60825-1: 2007. EN 60825-1: 2007 Safety of laser products. Part 1: Equipment classification and requirements: IEC 62366: 2007/ A 1 :2014; EN 62366: 2008 Medical devices-Application of usability engineering to medical devices, and with IEC 60601-1-6: 2010: EN 60601-1-6: 2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability.

Traditional 510k Submission Lite Touch™ Er YAG Laser Treatment System

Summary of Substantial Equivalence:

The submission and predicate device have substantially equivalent technical and performance characteristics including: power level; energy delivered; light wavelength delivered; aiming beam; laser medium; cooling methods; anatomical sites applicable; warnings and contraindications; and for use on the general population. The raw materials and electrical components of the submission and predicate device have a substantially equivalent design and operating controls.

Where there are differences between the submission and the predicate device K150140, a review of the data showed that the differences did not represent new unacceptable risk to the patient or operator of the device. After review of the subject and predicate devices, including technical, performance, and design information as mentioned above, it is concluded that the device in this 510(k) and the predicate device are substantially equivalent.