K111840

NOV 14 2011

510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 15 Network Drive
Burlington, MA 01803
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CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: November 7, 2011

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Emerge Fractional Laser

COMMON/USUAL NAME: Light and Laser System

CLASSIFICATION NAME: Laser surgical instrument for use in general and plastic surgery and in dermatology
(21 CFR § 878.4810)

PRODUCT CODES: GEX, ONG

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
Palomar Icon™ Aesthetic System
Lux1440 Handpiece
K103664

Palomar Medical Technologies, Inc.
LOI System (PaloVia™)
K090525

Reliant Technologies, Inc. (Now Solta Medical, Inc.)
Fraxel IV SR Laser System (Re:fine™)
K063808

Solta Medical, Inc.
Clear+Brilliant Laser System
K110349

4. INTENDED USE

The Emerge Fractional Laser is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. The Emerge Fractional Laser is further indicated for treatment of pigmented lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

5. DEVICE DESCRIPTION

The Emerge Fractional Laser consists of a fractional laser handpiece attached to a base unit. The base unit includes a power supply, control electronics, and user interface LCD screen.

6. SUBSTANTIAL EQUIVALENCE

The Emerge Fractional Laser is substantially equivalent to its predicate devices when used according to its intended use. The review of the technological characteristics, mechanism of action, indications for use, clinical data, histology data, and verification as well as validation information provided in the 510(k) Premarket Notification demonstrates that the Emerge Fractional Laser is substantially equivalent to its predicate device. Thus, substantial equivalence is therefore justified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Palomar Medical Technologies, Inc.
% Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs
15 Network Drive
Burlington, Massachusetts 01803

Re: K111840
Trade/Device Name: Emerge Fractional Laser
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: ONG
Dated: November 07, 2011
Received: November 09, 2011

Dear Ms. Timberlake:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111840

Device Name: Emerge Fractional Laser

Indications for Use:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111840