K101506

510(k) Summary

SEP 1 2010

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

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

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CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: June 24, 2010

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Lux1540, Lux1440, & Lux2940 Handpieces

COMMON/USUAL NAME: Dermatological and cosmetic laser

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

PRODUCT CODE: GEX, ONG

3. PREDICATE DEVICES

Palomar Erbium Handpiece (Lux2940 Handpiece)
K100270, K083900, K071768, K071152, K063571

Palomar Medical Technologies, Inc.
Lux1540 Handpiece
K100270, K090195, K091446, K080244, K060301

Palomar Medical Technologies, Inc.
Lux1440 Handpiece
K100270, K073583, K091446

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4. INTENDED USE

The Lux1540 and Lux2940 fractional combined treatment is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

The Lux1440 and Lux2940 fractional combined treatment is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

5. DEVICE DESCRIPTION

The complete platform consists of a cart, console with an internal power supply and electronics, chiller, and a footswitch. Each handpiece individually attaches to the console via a connection port.

6. PERFORMANCE DATA

Clinical studies were conducted to evaluate safety and effectiveness when combining either the Lux1540 and Lux2940 or the Lux1440 and Lux2940 for treatment of wrinkles, dyschromia and pigmented lesions. The specifications and indications for use of the handpieces are substantially equivalent to the predicate devices based on the data provided in Premarket Notification and comparison of the technical characteristics. Thus, these handpieces do not result in additional safety or effectiveness information.

7. SUBSTANTIAL EQUIVALENCE

The Lux1540, Lux1440 and Lux2940 Handpieces are substantially equivalent to their predicate devices when used according to its intended use. This decision is based on the information that is provided in this 510(k) Premarket Notification which demonstrates that the handpieces share the same technological characteristics, mechanism of action, intended use and physical properties when compared to their predicates.

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

SEP 1 2010

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

Re: K101506
Trade/Device Name: Lux1540. Lux1440 and Lux2940 Handpieces
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, ONG
Dated: June 28, 2010
Received: June 29, 2010

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

K101506

Indications for Use

SEP 1 2010

510(k) Number (if known): K101506

Device Name: Lux1540, Lux1440 and Lux2940 Handpieces

Indications for Use:

The Lux1540 and Lux2940 fractional combined treatment is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

The Lux1440 and Lux2940 fractional combined treatment is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MXM

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

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