K073583

510(k) Summary
Palomar Lux1440 Handpiece

MAR 2 6 2008

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

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 82 Cambridge Street
Burlington, MA 01803
Phone: (781) 993-2300
Fax: (781) 993-2330

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

DATE PREPARED: March 19, 2008

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar Lux1440 Handpiece

COMMON NAME: LUX1440

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

PRODUCT CODE: GEX

3. PREDICATE DEVICE

Palomar Erbium Fractional Handpiece
K071768
Palomar Medical Technologies, Inc.

Palomar Lux1540 Handpiece
K061652
Palomar Medical Technologies, Inc.

K073583

4. INTENDED USE

The Palomar Lux1440 Handpiece is intended for skin resurfacing procedures in addition to dermatological procedures requiring the coagulation of soft tissue.

5. DEVICE DESCRIPTION

The Palomar Lux1440 Handpiece attaches to the StarLux Pulsed Light and Laser System. The complete system consists of a cart, base unit, chiller, a footswitch, and a handpiece.

6. PERFORMANCE DATA

The review of the technical characteristics, indications for use, mechanism of action, and verification and validation information provided demonstrate that the modified Palomar Lux1440 Handpiece is substantially equivalent to its predicate device.

7. SUBSTANTIAL EQUIVALENCE

The Palomar Lux1440 Handpiece was found to be substantially equivalent to its predicate device when used according to its intended use. The information that is provided in this application demonstrates that the Palomar Lux1440 Handpiece also shares similar technological characteristics as its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2008

Palomar Medical Technologies, Inc.
% Sharon Timberlake, RAC, CCRA
Director of Regulatory Affairs
93 Cambridge Street
Burlington, Massachusetts 01803

Re: K073583
Trade/Device Name: PalmarLux 1440 Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 15, 2008
Received: February 19, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K073583

Device Name: PalomarLux1440 Handpiece

Indications for Use:

Dermatological procedures requiring the coagulation of soft tissue;

Skin resurfacing procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073583

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96