510(k) Summary
Lux1540™ Handpiece

K090195

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

1. SUBMITTER'S INFORMATION

NOV 20 2009

NAME: Palomar Medical Technologies, Inc.

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Burlington, MA 01803
Phone: (781) 993-2300
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CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: January 26, 2009

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar Lux1540™ Fractional Laser Handpiece

COMMON/USUAL NAME: Lux1540, Lux1540 Handpiece

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

PRODUCT CODE: GEX

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
Lux1540™ Fractional Laser Handpiece
K080244

Reliant Technologies, Inc.
Fraxel SR1500 Laser System (Fraxel Re:store™)
K070284

Cynosure, Inc.
Affirm Family Laser with XPL Handpiece
K080006

Global USA Distribution, LLC.
NannoLight IPL System
K082033

4. INTENDED USE

The Palomar Lux1540 Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures, treatment of melasma and striae, and treatment of acne scars and surgical scars.

5. DEVICE DESCRIPTION

The Lux1540 Handpiece attaches to the StarLux Pulsed Light and Laser Systems. The complete system consists of a cart, system console, chiller, a footswitch, and a handpiece.

6. PERFORMANCE DATA

The specifications and indications for use of the Lux1540 Handpiece are substantially equivalent to its predicate devices based on the data provided in the 510(k) premarket notification.

7. SUBSTANTIAL EQUIVALENCE

The Lux1540 Handpiece is substantially equivalent to its predicate devices when used according to its intended use. The information that is provided in this 510(k) premarket notification demonstrates that the Lux1540 Handpiece also shares the same technological characteristics, mechanism of action, intended use and physical properties to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Palomar Medical Technologies, Inc.
% Ms. Sharon Timberlake
Director of Regulatory Affairs
82 Cambridge Street
Burlington, Massachusetts 01803

NOV 20 2009

Re: K090195
Trade/Device Name: PalomarLux 1540™ Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in genera and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 23, 2009
Received: June 24, 2009

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 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 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): K090195

Device Name: PalomarLux1540™ Handpiece

Indications for Use:

The Palomar Lux1540™ Handpiece is intended for use in:

Coagulation of soft tissue;
Skin resurfacing procedures;
Treatment of melasma and striae;
Treatment of acne scars and surgical scars.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Per 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)

for mxn

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

510(k) Number K090195