510(k) Summary
Lux2940 Handpiece

K063571

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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Burlington, MA 01803
Phone: (781) 993-2300
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FEB 9 2007

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

DATE PREPARED: November 28, 2006

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar Lux2940 Handpiece

COMMON/USUAL NAME: Er: YAG laser

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

Friendly Light (K000023)
Innotech USA

Contour Profile (K010285 & K040005)
Sciton, Inc.

Harmony Lovely II (K042000)
Alma Lasers Inc. (formerly MSq (M2) Ltd.)

Dermablate (K980361)
Aesculap-Meditec

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4. INTENDED USE

Intended for coagulation, vaporization, ablation and/or cutting of soft tissue. This includes skin resurfacing, treatment of wrinkles, epidermal nevi, Telangiectasia, spider veins, actinic chelitis, keloids, Verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors, debulking cysts and superficial skin lesions

5. DEVICE DESCRIPTION

The Lux2940 handpiece is composed of a system console, cooling system, power supply and handpiece.

6. PERFORMANCE DATA

The specifications and indications for use of the Lux2940 are substantially equivalent to its predicate devices. Thus, do not result in additional safety or effectiveness information.

7. SUBSTANTIAL EQUIVALENCE

The Lux2940 handpiece is substantially equivalent to its predicate devices when used according to its intended use. The information that is provided in this application demonstrates that the Lux2940 also share the same technological characteristics to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 9 2007

Re: K063571
Trade/Device Name: Palomar Lux2940 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: November 27, 2006
Received: November 29, 2006

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

For Palo

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): K063571

Device Name: Palomar Lux2940 Handpiece

Indications for Use:

The Palomar Lux2940 handpiece is intended for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs, and glands in the following indications:

- Skin resurfacing
- Treatment of wrinkles
- Epidermal nevi
- Telangiectasia
- Spider veins
- Actinic chelitis
- Keloids
- Verrucae
- Skin tags
- Anal tags
- Keratoses
- Scar revision (including acne scars)
- Debulking benign tumors
- Debulking cysts
- Superficial skin lesions

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use

510(k) Number K063571

(Optional Format 1-2-96)