510(k) Summary

K120622

MAY 23 2012

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
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CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Vice President of Global Regulatory & Quality Affairs

DATE PREPARED: February

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar Vectus™ Laser

COMMON/USUAL NAME: Diode Laser System

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

Lumenis, Inc.
LightSheer Duet Laser System
K053628

Milesman, S.L.
Milesman Premium Pulsed Diode Array Laser
K073300

Sandstone Medical Technologies, Inc.
The Cheveux Diode Laser System
K100893

Palomar Medical Technologies, Inc.
Skintel™ Reader
K110907

K120622

4. INTENDED USE

The Palomar Vectus Laser is intended for use in aesthetic, dermatology, general and plastic surgery applications for the treatment of vascular lesions, such as angiomas, hemangiomas, telangiectasia and other benign vascular lesions. Additionally, treatment of leg veins, benign pigmented lesions, hair removal and permanent hair reduction as well as pseudofollilculitis barbae. Treatment for these indications is intended for all Fitzpatrick skin types, including tanned skin.

The Skintel™ Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence.

5. DEVICE DESCRIPTION

The Palomar Vectus Laser consists of a diode-powered handpiece, Skintel Reader, base module, coolant reservoir, and chiller module. The handpiece connects to the base module via the umbilical.

6. PERFORMANCE DATA

The review of the technical characteristics, indications for use, verification and validation information provided in the 510(k) Premarket Notification demonstrates that the Palomar Vectus Laser is substantially equivalent to its predicate devices. Additionally, clinical data to support the use of the Skintel Reader when used with the Palomar Vectus Laser was also included.

7. SUBSTANTIAL EQUIVALENCE

The Palomar Vectus Laser is substantially equivalent to its predicate devices when used according to its intended use. This is based on the information provided in this 510(k) Premarket Notification which demonstrates that the Palomar Vectus Laser shares the same technological characteristics, mechanism of action, intended use and physical properties when compared to its 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

MAY 23 2012

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

Re: K120622
Trade/Device Name: Palomar Vectus Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and in plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 29 , 2012
Received: March 01, 2012

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): K120622

Device Name: Palomar Vectus Laser

Indications for Use:

The Palomar Vectus Laser is intended for all Fitzpatrick skin types, including tanned skin for use in aesthetic, dermatology, general and plastic surgery applications for the treatment of:

- The treatment of vascular lesions, such as angiomas, hemangiomas, telangiectasia and other benign vascular lesions.
- Treatment of leg veins.
- The treatment of benign pigmented lesions.
- Hair removal and permanent hair reduction.
- Treatment of pseudofolliculitis barbae.

The Skintel™ Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence.

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 mxm

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

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