K110907

510(k) Summary

JUN 2 2 2011

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

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 15 Network Drive
Burlington, MA 01803
Phone: (781) 993-2300
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CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: June 14, 2011

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Palomar Icon™ Aesthetic System

COMMON/USUAL NAME: Light and Laser System

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

PRODUCT CODES: GEX, ONG

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
Artisan System (Lux1540, Lux1440, Lux2940, MaxG)
K100270

Palomar Medical Technologies, Inc.
Combination Fractional Treatment
(Lux1540, Lux1440, Lux2940)
K101506

Palomar Medical Technologies, Inc.
Lux1064 Handpiece
K041879

Palomar Medical Technologies, Inc.
LuxIR Handpiece
K070298

K110907

Palomar Medical Technologies, Inc.
Palomar StarLux System
Intense Pulsed Light Handpieces
K041086, K033549

4. INTENDED USE

The 2940 Ablative Laser 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 and superficial skin lesions.

The 2940 Fractional Ablative Laser Handpiece 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, pigmented lesions, and vascular dyschromia.

The 1540 Fractional Non-ablative Laser Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

The 1440 Fractional Non-ablative Laser Handpiece is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures.

The 1540 and 2940 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 1440 and 2940 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 IR Handpiece is intended for photocoagulation of soft tissue in dermatologic applications. In addition, it is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

The 1064 Laser Handpiece is intended for the removal of unwanted hair for skin types I-VI, and to effect stable long-term permanent hair reduction; treatment of benign pigmented lesions such as, but not limited to, senile lentigines (age spots), solar lentigos (sun spots), pigmented seborrheic keratoses, nevi, chloasma, cafe-au-lait macules, and plaques; verrucae, skin tags, seborrheic keratosis; tattoos (significant reduction in the intensity of black and/or blue-black tattoos); pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser/light treatments; treatment of vascular lesions such as but not limited to, port wine stains, hemangiomas, telangiectasias, rosacea, venus lake, facial and leg veins; reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar; coagulation and hemostasis of soft tissue; treatment of wrinkles and pseudofolliculitis barbae (PFB).

The Max Series Intense Pulsed Light Handpieces are intended for the treatment of inflammatory acne (acne vulgaris) and for the treatment of benign pigmented epidermal and cutaneous lesions, including warts, scars and striae; removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction; treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait; and treatment of vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.

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 Icon Aesthetic System consists of a console with an internal power supply, chiller, and electronics. The light and laser handpieces individually connect to the system via the console connection port.

6. PERFORMANCE DATA

The review of the technical characteristics, indications for use, clinical data, verification and validation information provided in the 510(k) Premarket Notification demonstrates that the Palomar Icon Aesthetic System is substantially equivalent to its predicate device.

7. SUBSTANTIAL EQUIVALENCE

The Palomar Icon Aesthetic System 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 Icon Aesthetic System 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

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

JUN 22 2011

Re: K110907
Trade/Device Name: Palomar Icon™ Aesthetic System
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: March 30, 2011
Received: March 31, 2011

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,

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

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

510(k) Number K110907

510(k) Number (if known): K110907

Device Name: Palomar Icon™ Aesthetic System

Indications for Use:

The 2940 Ablative Laser 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 and superficial skin lesions.

The 2940 Fractional Ablative Laser Handpiece 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, pigmented lesions, and vascular dyschromia.

The 1540 Fractional Non-ablative Laser Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

The 1440 Fractional Non-ablative Laser Handpiece is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures.

The 1540 Fractional Non-ablative Laser and 2940 Fractional Ablative Laser Handpiece 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 1440 Fractional Non-ablative Laser Handpiece and 2940 Fractional Ablative Laser Handpiece 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 MaxIR Handpiece is intended for photocoagulation of soft tissue in dermatologic applications. In addition, it is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the

temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

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The Max Series Intense Pulsed Light Handpieces are intended for the treatment of inflammatory acne (acne vulgaris) and for the treatment of benign pigmented epidermal and cutaneous lesions, including warts, scars and striae; removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction; treatment of benign pigmented lesions, including lentigines, nevi, melasma, and cafe-au-lait; and treatment of vascular lesions, including port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.

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)

for mkn

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

510(k) Number K110907