510(k) Summary

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: January 25, 2010

2. **DEVICE INFORMATION**

   TRADE/PROPRIETARY NAME: Artisan™ 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.
   Lux2940 Handpiece
   K083900, K071768
   
   Palomar Medical Technologies, Inc.
   Lux1540 Handpiece
   K090195, K091446
   
   Palomar Medical Technologies, Inc.
   Lux1440 Handpiece
   K073583, K091446
   
   Palomar Medical Technologies, Inc.
   Palomar StarLux Pulsed Light System
   K041086, K033549
4. **INTENDED USE**

The Lux1540 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 Lux1440 Handpiece is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures.

The 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 and superficial skin lesions. The Lux2940 Fractional 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 MaxG Handpiece is intended for treatment of benign pigmented epidermal and cutaneous lesions, including but not limited to lentigines, nevi, melasma, café-au-lait warts, scars, striae, and the treatment of vascular lesions including but not limited to port wine stains, hemangiomas, angiomas, telangiectasias, rosacea, facial and leg veins.

5. **DEVICE DESCRIPTION**

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

6. **PERFORMANCE DATA**

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

7. **SUBSTANTIAL EQUIVALENCE**

The Artisan 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 Artisan Aesthetic System shares the same technological characteristics, mechanism of action, intended use and physical properties when compared to its predicates.
Palomar Medical Technologies, Inc.  
% Ms. Sharon Timberlake, MSHS, RAC, CCRA  
15 Network Drive  
Burlington, Massachusetts 01803

Re: K100270  
Trade/Device Name: Artisan™ 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, ONF  
Dated: January 28, 2010  
Received: January 29, 2010

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" (21 CFR 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

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): K106170

Device Name: Artisan<sup>TM</sup> Aesthetic System

Indications for Use:

The Lux2940 Fractional Handpiece optics 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 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 and superficial skin lesions.

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The Lux1540 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.

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

510(k) Number K106270
The MaxG Handpiece is intended for treatment of benign pigmented epidermal and cutaneous lesions, including but not limited to lentigines, nevi, melasma, café-au-lait warts, scars, striae, and the treatment of vascular lesions including but not limited to port wine stains, hemangiomas, angiomas, telangiectasias, rosecea, facial and leg veins.

Prescription Use  X  AND/OR  Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D)  (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten signature]
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number  K100270

Palomar Medical Technologies, Inc.
Artisan Aesthetic System