K 061436

## 510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the Q-YAG 5™ Nd:YAG Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

| | |
|---|---|
| Applicant: | Palomar Medical Technologies, Inc. |
| Address: | 82 Cambridge St.<br>Burlington, MA 01803 |
| Contact Person: | Sharon L. Timberlake |
| Telephone: | 781-993-2414 |
| Preparation Date: | 5-23-06 |
| Device Trade Name: | Palomar Q-YAG 5™ Nd:YAG Laser System |
| Common Name: | Q:Switched Nd:YAG |
| Classification Name: | Laser surgical instrument for use in General and Plastic Surgery and in Dermatology<br>(see: 21 CFR 878.4810). |
| Product Code: | GEX |
| Legally-Marketed Predicate Device: | Continuum Electro-Optics, Inc. Medlite™ $C^3$ Q-Switched:Nd:YAG Laser<br>Palomar Q-YAG 5™ Nd:YAG Laser System |
| System Description: | The complete system consists of a power supply unit, a cooling unit, a foot switch, and the handpiece that connects the laser unit and cooling unit using an umbilical cord. In standard use, the handpiece is held against the treatment area and the light pulse is delivered when the foot-switch is depressed. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit. |

DEC - 6 2006

| | |
|---|---|
| Intended Use of the Device: | The Palomar Q-YAG 5™ Nd:YAG laser system is indicated at the 1064 nm wavelength for skin resurfacing with or without adjuvant preparation, dark ink tattoo removal (e.g., black ink), removal of pigmented lesions, including, but not limited to, lentigines, nevi, melasma, and café-au-lait, and the removal or lightening of hair. The 532 nm wavelength is indicated for the removal of red ink tattoos, treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, portwine stains, and most pigmented lesions (e.g., lentigines, ephlides). The 1064/532 nm blended wavelength is indicated for tattoo removal. |
| Performance Data: | The device complies with the following U.S. Food and Drug Administration performance standards: 21 CFR §1040.10 & 1040.11. The data presented in the 510(k) premarket notification support the safety and effectiveness of the device and do not raise new questions of safety or efficacy. |
| Conclusion: | Based on the foregoing, the Palomar Q-YAG 5™ Nd:YAG Laser System is substantially equivalent to its legally-marketed predicate devices. |

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

DEC - 6 2006

Re: K061436
Trade/Device Name: Q-YAG 5™ Nd:YAG laser system
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: October 10, 2006
Received: October 11, 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

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 Statement

510(k) Number (if known): K 061436

Device Name: Q-YAG 5™ Nd:YAG laser system

Indications for Use:

The Palomar Q-YAG 5™ Nd:YAG laser system is indicated at the 1064 nm wavelength for skin resurfacing with or without adjuvant preparation, dark ink tattoo removal (e.g., black ink), removal of pigmented lesions, including, but not limited to, lentigines, nevi, melasma, and café-au-lait, and the removal or lightening of hair. The 532 nm wavelength is indicated for the removal of red ink tattoos, treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, portwine stains, and most pigmented lesions (e.g., lentigines, ephlides).

The 1064/532 nm blended wavelength is indicated for tattoo removal.

(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 ✓ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

**510(k) Number** K061436 (Optional Format 1-2-96)