MAR 2 3 2006

Attachment 4

510(K) Summary of Safety and Effectiveness K060301

This 510(K) Summary of Safety and Effectiveness for the Palomar Lux1540 handpiece 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. Burlington, MA 01803
Contact Person:	Marcy Moore
Telephone:	919-363-2432
Preparation Date:	February 2, 2006
Device Trade Name:	Palomar Lux1540 Handpiece
Common Name:	Lux1540
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and Dermatology (21 CFR 878.4810)
Product Code:	GEX
Legally-Marketed Predicate Device:	Reliant Fraxel K031795

System Description:

The Palomar Lux1540 Handpiece delivers light with a wavelength of 1540 nm. The complete system consists of a power source, chiller, a footswitch, and a handpiece connected to the power unit with an umbilical. In standard use, the handpiece is held in firm contact with the skin. The handpiece tip is water-cooled to offer active skin cooling. System parameters and other system features are controlled from the user interface panel on top of the power unit.

Intended Use of the Device:	Dermatological procedures requiring the coagulation of soft tissue.
Performance Data:	Performance data was provided showing the Lux1540 is capable of performing fractional photothermolysis, i.e., creation of a pattern (lattice) of microscopic islets of damage at superficial skin layers.
Conclusion:	Based on the foregoing, the Palomar Lux1540 Handpiece is substantially equivalent to the legally-marketed claimed predicate device, namely the Reliant Laser System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

Palomar Medical Technologies, Inc.
c/o Ms. Marcy Moore
Manager of Clinical Studies
131 Kelekent Lane
Cary, North Carolina 27511

Re: K060301
Trade/Device Name: Palomar Lux1540 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: February 2, 2006
Received: February 6, 2006

Dear Ms. Moore:

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.

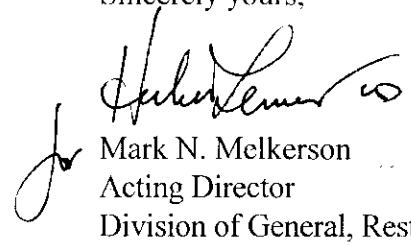
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting 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): K060301

Device Name: Palomar Lux1540 Handpiece

Indications for Use:

Dermatological procedures requiring the coagulation of soft tissue.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060301