DEC 0 6 2001

Attachment 4

510(K) Summary of Safety and Effectiveness K013028

This 510(K) Summary of Safety and Effectiveness for the SLP™ 1000 Diode Array 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. Burlington, MA 01803
Contact Person:	Marcy Moore
Telephone:	919-363-2432
Preparation Date:	September 4, 2001
Device Trade Name:	Palomar SLP™ 1000
Common Name:	Super Long Pulse Diode Laser
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see: 21 CFR 878-4810). Product Code: GEX Panel: 79
Legally-Marketed Predicate Device:	LightSheer Diode Array Laser Laserscope Lyra G Surgical Laser System
System Description:	The SLP™ 1000 delivers infrared laser light with a wavelength of 810 nm, a selectable pulse duration of 50 – 1000 ms, and a selectable pulse energy of .5-100 J. The complete system consists of a power unit, chiller, a footswitch, and a handpiece connected to the laser unit with an umbilical. In standard use, the handpiece is pressed against the patient's skin and a light pulse is delivered when the footswitch is depressed. The handpiece tip is water-cooled to

	provide active skin cooling. Laser parameters and other system features are controlled from the user interface panel on top of the power unit, which provides an interface to the system computer.
Intended Use of the Device:	The SLP™ 1000 Diode Laser System is indicated for the treatment of pseudofolliculitis barbae, as well as hair removal, permanent hair reduction, treatment of pigmented and vascular lesions (including facial and leg veins).
Performance Data:	The differences in the specifications of the SLP™ 1000 laser and the predicate device do not result in different performance or raise new questions of safety or efficacy.
Conclusion:	Based on the foregoing, the SLP™ 1000 Diode Laser System is substantially equivalent to the legally-marketed claimed predicate device for permanent hair reduction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Palomar Medical Products, Inc.
c/o Ms. Marcy Moore
131 Kelekent Lane
Cary, North Carolina 27511

Re: K013028
Trade Name: Palomar SLP™ 1000 Diode Laser System
Regulation Number: 878.4810
Regulation Name: Laser Surgical Instrument
Regulatory Class: II
Product Code: GEX
Dated: September 6, 2001
Received: September 10, 2001

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walker, MD

Celia M. Witten, Ph.D., M.D.
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: K013028

Device Name: Palomar SLP™ 1000

Indications for Use:

The Palomar Super Long Pulse, SLP™ 1000, diode laser system is indicated for the treatment of pseudofolliculitis barbae in Skin Types I-VI.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

Susan Walker, MD
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013028