2/4/99

K982980

Attachment 2

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the LightSheer™ Long Pulse Ruby Laser 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 Products Anthony Fiorillo, President
Address:	45 Hartwell Avenue Lexington, MA 02 781-676-7300
Contact Person:	Marcy Moore Manager of Clinical Studies
Telephone:	919-676-7166
Fax:	919-676-3683
Preparation Date:	August 24, 1998
Device Trade Name:	LightSheer™ Long Pulse Ruby Laser
Common Name:	Ruby Laser, long pulse
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 ™ Long Pulse Ruby Laser** Palomar Medical Products k980420 **EpiLaser® Normal Mode Ruby Laser** Palomar Medical Products k980517
System Description:	The LightSheer™ operates at a wavelength of 694.3 nanometers and the beam has a pulse duration of 3 and 20 milliseconds. Energy fluences of 10-60 J/cm^2

	are achieved under conditions of intended use. A thermoelectrically cooled handpiece is held firmly against the treatment site.
Intended Use of the Device:	The LightSheer™ is intended to effect temporary hair reduction in skin types I-IV. The LightSheer™ is also intended to effect stable long-term, or permanent, hair reduction in skin types I-IV through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.
Performance Data:	There are no technological differences.
Clinical Data:	None required.
Conclusion:	Based on the foregoing, the LightSheer™ is effective for producing a stable long-term, permanent reduction of hair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1999

Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Products, Inc.
9516 Candor Oaks Drive
Raleigh, North Carolina 27615

Re: K982980
Trade Name: LightSheer™ Long Pulse Ruby Laser
Regulatory Class: II
Product Code: GEX
Dated: January 11, 1999
Received: January 12, 1999

Dear Ms. Moore:

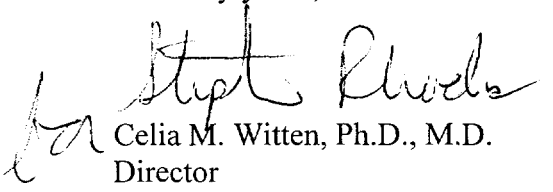
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K982980

Device Name: LightSheer ™ Long Pulse Ruby Laser

Indications for Use:

The LightSheer™ is intended to effect temporary hair reduction in skin types I-IV. The LightSheer™ is also intended to effect stable long-term, or permanent, hair reduction in skin types I-IV through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ___
(per 21 CFR 801.109)

Sign-Off) K982980
(Division
Division of General Restorative Devices
510(k) Number