K980420

APPENDIX F

MAY 4 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

LightSheer™ Long Pulse Ruby Laser

This 510(k) summary of safety and effectiveness is provided in accordance with the requirements of SMDA 1990 following Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Palomar Medical Technologies, Inc.
Address:	45 Hartwell Avenue Lexington, MA 02173
Contact Person:	Mr. Steven Armstrong Vice President of Quality Assurance and Service ~~President~~, Palomar Medical Technologies, Inc.
Telephone:	781-676-7300 781-676-7330 (Fax)
Preparation Date: (of the Summary)	January 30, 1998
Device Trade Name:	LightSheer™
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 devices	The LightSheer™ is substantially equivalent to the EpiLaser®.
Device Description:	LightSheer™ laser is a long pulse ruby laser which delivers its energy to the treatment site via two quartz fiber optics. The beam exits from a chilled hand piece which is held in firm contact with the skin at the treatment site.

Intended Use of	The LightSheer™ is intended to effect hair removal of patients with skin types 1 - 4 through selective targeting of melanin in hair follicles. The LightSheer™ is a prescription device (12 CFR 801.109)
Comparison:	The specifications, performance and intended use of the LightSheer™ are the same or similar as the EpiLaser® described in K963947. The differences between the lasers are not significant in terms of the performance or intended use of the LightSheer™
Performance Data:	None required.
SUMMARY:	The similarities of the LightSheer™ and the EpiLaser® demonstrate that the two lasers are substantially equivalent. The differences between the LightSheer™ and EpiLaser® do not pose any significant or deleterious effects on either the safety, performance, use, or effectiveness of the LightSheer™. The fluences to tissue at the treatment site are the same for the LightSheer™ and the EpiLaser®.
Additional: Information	None requested
CONCLUSION:	The LightSheer™ long pulse ruby laser is substantially equivalent to the EpiLaser®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 4 1998

Mr. Steven Armstrong
Vice President of Quality Assurance and Service
Palomar Medical Technologies, Incorporated
45 Hartwell Avenue
Lexington, Massachusetts 02173

Re: K980420
Trade Name: LightSheer™ Long Pulse Ruby Laser
Regulatory Class: II
Product Code: GEX
Dated: February 2, 1998
Received: February 3, 1998

Dear Mr. Armstrong:

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,

for 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

APPENDIX C

INDICATIONS FOR USE

510(k) Number: K980420

Device Name: LightSheer™ Long Pulse Ruby Laser

Indications for Use:

The LightSheer™ is intended to effect hair removal of patients with skin types 1 - 4 through selective targeting of melanin in hair follicles.

Note: The EpiLaser® was limited to prescription use at the time of the substantially equivalent decision. (March 5, 1997). Palomar Medical Technologies, Inc. proposes that the LightSheer™ be a limited to prescription use also.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980420