JUL 21 1998

K980517

Attachment 6

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EpiLaser™ Normal Mode 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
Address:	45 Hartwell Avenue Lexington, MA 02
Contact Person:	Tony Fiorillo
Telephone:	781-676-7300
Preparation Date:	February 3, 1998
Device Trade Name:	EpiLaser™ Normal Mode Ruby Laser
Common Name:	Ruby 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:	EpiLaser™ Normal Mode Ruby Laser Palomar Medical Products k963947
System Description:	The EpiLaser™ operates at a wavelength of 694.3 nanometers and the beam has a pulse duration of 0.2 to 3.0 milliseconds (msec). The laser energy is delivered to the treatment sites by an articulated arm. Energy fluences of 10-60 J/cm^2 are achieved under conditions of intended use. A water-cooled handpiece (spot sizes of 7 or 10 mm) is held firmly against the treatment site.

Intended Use of the Device:	The EpiLaser™ Normal Mode Ruby Laser is intended to effect a permanent reduction of hair in patients with skin types I-IV through selective targeting of melanin in hair follicles.
Performance Data:	There are no technological differences.
Results of Clinical Study:	Observations of hair and skin responses were recorded prior to treatment and at 1, 3, 6, 9, 12 and 24 months after treatment. There was no scarring or depigmentation of the skin in any subject. The study demonstrated that EpiLaser™ is a safe and effective tool for hair removal, resulting in a permanent reduction of hair.
Conclusion:	Based on the foregoing, the EpiLaser™ is effective for producing a permanent reduction of hair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1998

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

Re: K980517
Trade Name: EpiLaser™ Normal Mode Ruby Laser
Regulatory Class: II
Product Code: GEX
Dated: June 12, 1998
Received: June 15, 1998

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 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). Permanent hair reduction, in the context of this indication for use, shall mean a long term, stable reduction in the number of hairs regrowing after a treatment regime. It shall not permit a claim using the terms permanent elimination or permanent removal of all hair in the treated area after a treatment. 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 requirements, 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" (21CFR 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/dsma/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

K980517

INDICATIONS FOR USE

The EpiLaser® is intended to effect temporary hair reduction in skin types I-IV. The EpiLaser® 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.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980517