

MAR 10 1998

K980160

APPENDIX E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

Epilaser<sup>®</sup> I Normal Mode Ruby Laser

This 510(k) summary of safety and effectiveness involves a post-sale upgrade of the Epilaser<sup>®</sup> I and is submitted 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. Anthony Fiorillo  
President, Palomar Medical  
Technologies, Inc.

Telephone: 617-676-7300  
617-676-7330 (Fax)

Preparation Date: December 1997  
(of the Summary)

Device Trade Name: Upgrade for the Epilaser<sup>®</sup> I (an accessory to the Epilaser<sup>®</sup> I).

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 devices: The Epilaser<sup>®</sup> I is the legally marketed device. Installation of

Description of the Device: The upgrade kit for the Epilaser<sup>®</sup> I consists of a laser head with a slightly higher energy output, a fiber optic beam connector with a standard SMA 905 connector, a fiber optic, and modified hand pieces adapted with a quick connect to the fiber optic.

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Intended Use of  
of the Device:

The intended use Epilaser<sup>R</sup> I is not affected by installation of  
the upgrade kit.

Comparison:

The operational specifications, performance and intended use  
of the Epilaser<sup>R</sup> I are not affected by the installation of the  
upgrade kit. The changes in specifications after installation of  
the upgrade kit, e.g., a fiber optic in place of an articulated  
arm, do not affect the performance characteristics of the  
Epilaser<sup>R</sup> I.

Performance Data:

None required.

SUMMARY:

Installation of the upgrade kit has no effect on the  
performance, instructions for use, or indications of use for the  
Epilaser<sup>R</sup> I.

The Epilaser<sup>R</sup> I performance and characteristics are not  
affected by the installation of the upgrade kit.

CONCLUSION:

The Epilaser<sup>R</sup> I laser after installation of the kit is substantially  
equivalent to the Epilaser<sup>R</sup> I prior to installation of the kit.

Additional:  
Information

None requested



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 10 1998

Mr. Anthony Fiorillo  
President  
Palomar Medical Technologies, Incorporated  
45 Hartwell Avenue  
Lexington, Massachusetts 02173

Re: K980160  
Trade Name: Epilaser I Upgrade Kit  
Regulatory Class: II  
Product Code: GEX  
Dated: January 13, 1998  
Received: January 16, 1998

Dear Mr. Fiorillo:

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.

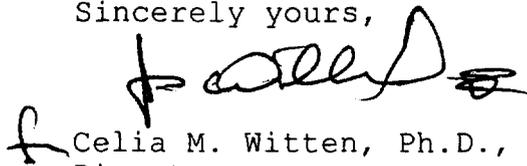
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Fiorillo

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,

  
f 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

K 980160

APPENDIX D

NOTE: The following indications for use are quoted from the Indications for Use statement for the Epilaser<sup>R</sup> as described in K963947 (the laser has been renamed the Epilaser<sup>R</sup> I). The indications for use in this APPENDIX are provided for the record; the installation of the upgrade kit does not affect or alter these indications. The upgrade kit itself does not have indications for use.

510(k) Number: ~~K963947~~ \_\_\_\_\_

Device Name: Epilaser<sup>R</sup> I Normal Mode Ruby Laser

Indications for Use:

The Epilaser<sup>R</sup> I is intended to effect hair removal of patients with skin types 1 - 4 through selective targeting of melanin in hair follicles in dermatology and plastic surgery.

The Epilaser<sup>R</sup> I was limited to prescription use at the time of the substantially equivalent decision. (March 5, 1997).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_

[Signature]  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K980160

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