JAN 2 7 2000 K991935

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's name: ESC Medical Systems, Ltd

Submitter's address: Yokneam Industrial Park
PO Box 240
Yokneam 20692
ISRAEL

Telephone: 011-972-4-959-9000

Fax: 001-972-4-959-9050

Names of devices: EpiLight®, PhotoDerm® HR

Predicate devices:

1) EpiLight® Hair Removal System, made by ESC Medical Systems of Yokneam, ISRAEL. 510(k) #K963249
2) PhotoDerm® HR , Made by ESC Medical Systems of Yokneam, ISRAEL. 510(k) #K974536
3) EpiLaser™ Normal Mode Ruby Laser made by Palomar Medical Products of N. Carolina USA. 510(k) #980517.
4) LightSheer™ Long Pulse Ruby Laser made by Palomar Medical Products of N. Carolina USA. 510(k) #982980.
5) LightSheer™ Pulsed Diode Array Laser System made by Star Medical Technologies of Pleasanton CA, USA 510(k) #K982940.

Description of device:
EpiLight® and PhotoDerm® HR are electro-optical medical devices designed for effective photothermal treatment of unwanted hair and its removal.

Summary:
Pursuant to section 513(I) of the Safe Medical Devices Act of 1990, ESC Medical Systems has elected to include in this premarket notification a Summary of Safety and Effectiveness upon which we believe a substantial equivalence determination for the EpiLight® Hair Removal System and the PhotoDerm® HR can be based.

Intended use:
EpiLight® and PhotoDerm® HR are used for the removal of unwanted hair.
EpiLight® and PhotoDerm® HR are also intended to effect stable long-term, or permanent hair reduction in skin types I-V 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.

Comparing technical characteristics:

Both a technical comparison and clinical trials were performed by ESC Medical Systems to establish the substantial equivalence to the predicate devices.

No performance standards applicable to the PhotoDerm® HR have been adopted under Section 514 of the Act.

In summary we believe that the analysis and clinical data establish that the PhotoDerm® HR is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 7 2000

Dr. Zvi Ladin
Corporate Vice President, Clinical and
Regulatory Affairs
ESC Medical Systems LTD
U.S. Operations
250 First Avenue
Needham, Massachusetts 02494

Re: K991935
Trade Name: Epiderm Hair Removal System and
PhotoDerm Hair Removal System
Regulatory Class: II
Product Code: GEX
Dated: October 26, 1999
Received: October 27, 1999

Dear Dr. Ladin:

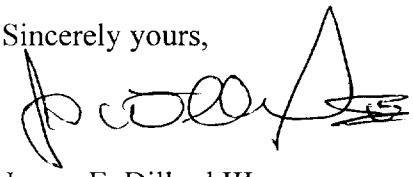
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991935

Device Name: ESC Family of Intense Pulsed Light Hair Removal Systems: EpiLight® and PhotoDerm® HR

Indications For Use:

EpiLight®

EpiLight® is used for the removal of unwanted hair.

EpiLight® is also intended to effect stable long-term, or permanent hair reduction in skin types I-V 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.

PhotoDerm® HR

PhotoDerm® HR is used for the removal of unwanted hair.

PhotoDerm® HR is also intended to effect stable long-term, or permanent hair reduction in skin types I-V 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991935

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)