K 963249

1. 510(K) SUMMARY- SUMMARY OF SAFETY AND EFFECTIVENESS

JUL - 7 1997

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

Name of device: EpiLight™ Hair Removal System

Predicate devices:

1. LT-100 ND:YAG Laser Hair Removal System made by Thermolase Corporation of San Diego, California. 510K #K950019.
2. Epilator 629 made by American Hair Removal System of Southern Pines, North Carolina. 510K #K892514.

Description of device:
EpiLight™ Hair Removal System is an electro optic medical device designed for effective photothermal treatment of unwanted hair and its long-term 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 can be based.

It is our understanding that there are presently no FDA regulations describing the form and content of such Summaries. With this in mind, ESC Medical Systems has tried to anticipate what information may be of particular interest to the agency regarding safety and effectiveness of the PhotoDerm® PL.

Intended use:
The EpiLight™ Hair Removal System is intended for long term removal of unwanted hair. The LT-100 ND:YAG Laser Hair Removal System made by Thermolase Corporation of San Diego, California. 510K #K950019 was classified as a class II medical device by the General and Plastic Surgery Devices Panel. The AHRS Epilator 629 was classified as class III medical device by General and Plastic Surgery Devices Panel. ESC Medical Systems' EpiLight™ Hair Removal System is substantially equivalent to these devices.

Comparing technical characteristics:

Both a technical comparison and clinical trials were performed by ESC Medical Systems to establish this equivalence:

ESC has performed a detailed comparison of the technical specifications of predicate device #1 and the EpiLight™ Hair Removal System. The results have documented that the system specifications of EpiLight™ are well within the range of the technical specifications of predicate device #1.

A theoretical study was conducted to establish the temperature distribution resulting from a treatment of a hair follicle by the EpiLight™ Hair Removal System.. The temperatures reached as a result of exposure to the light energy of system, was evaluated. It is the view of ESC Medical Systems that this analysis demonstrates that the EpiLight™ Hair Removal System is an effective way of long term removal of unwanted hair, and is safe in minimizing the adverse effects in the surrounding tissues.

Performance:
In addition, ESC Medical Systems has also conducted a multi-center clinical study in which unwanted hair was treated by the EpiLight™ Hair Removal System. This study was analyzed and the clearance rates and rate of occurrence of adverse effects of the EpiLight™ Hair Removal System were established. This data was compared to published data on the clearance rate and adverse effects of predicate devices. It is ESC's opinion that this comparison demonstrates that the EpiLight™ Hair Removal System is as safe and as effective as the predicate devices in the long term removal of unwanted hair.

No performance standards applicable to the EpiLight™ Hair Removal System have been adopted under Section 514 of the Act. However,

1.The EpiLight™ Hair Removal System is an electro medical device and conforms with the voluntary international standard IEC601.1-1, Medical Electrical Equipment, Part 1: General Requirements for Safety.

2. Although the EpiLight™ Hair Removal System is not a laser device, substantial equivalence to a laser device is being claimed. As such ESC has made efforts to comply, where applicable, with 21 CFR 1040.1 FDA laser performance standard.

In summary we believe that the analysis, the clinical data and the standards which the EpiLight™ Hair Removal System meets make it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Zvi Ladin
Vice President
ESC Medical Systems
Yokneam Industrial Park
PO Box 240
Yokneam 20692, Israel

JUL - 7 1997

Re: K963249
Trade Name: EpiLigh™ Hair Removal System
Regulatory Class: II
Product Code: GEX
Dated: June 9, 1997
Received: June 10, 1997

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 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" (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

510(k) Number (if known): K963249

Device Name: EpiLigh™ Hair Removal System

Indications For Use:

The EpiLight™ Hair Removal System is used for the removal of unwanted hair

(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 K963249

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)