K994014

510(K) PREMARKET NOTIFICATION
Hair removal for skin type VI patients
ESC Medical Systems Ltd.

FEB 24 2000

510(K) Summary

Submitter:	ESC Medical Systems Ltd. Yokneam Industrial Park Yokneam,20692, Israel Phone: 972-4-959-9000 Fax: 972-4-959-9050
Contact:	Dr. Zvi Ladin, VP, Clinical Applications and Regulatory Affairs ESC Inc. 250 First Avenue Needham, MA 02495 Phone: 781-444-8446 Fax: 781-444-8812
Date summary prepared:	November 23, 1999
Device Trade Name:	IPL™ Device for hair removal
Common name:	EpiLight®; MultiLight™
Classification name:	Laser instrument, powered, surgical (class II medical device)
Equivalent Devices:	ESC EpiLight® Hair Removal System ESC PhotoDerm® HR
Clinical Information:	A multi-center study was conducted to examine the clinical effectiveness of IPL™ devices in the removal of unwanted her. The study documented the clearance rate and the adverse effects obtained when treating skin type VI patients using an IPL™ device.
Intended Use:	Removal of unwanted hair in patients with skin type VI
Conclusion:	IPL™ devices used to treat skin type VI patients are substantially equivalent in their level of safety and effectiveness to that obtained when using the same devices to treat patients with skin types I – V
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2000

Dr. Zvi Ladin
Corporate Vice President
Clinical and Regulatory Affairs
ESC Medical Systems Ltd.
250 First Avenue, Suite 300
Needham, Massachusetts 02494

Re: K994014
Trade Name: EpiLight® and MultiLight™
Regulatory Class: II
Product Code: GEX
Dated: November 24, 1999
Received: November 26, 1999

Dear Dr. Ladin:

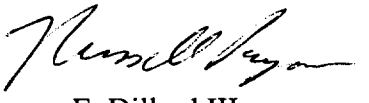
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



for 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): K994014

Device Name: ESC Intense Pulsed Light Systems: EpiLight® and MultiLight™

Indications For Use:

ESC Intense Pulsed Light Systems: EpiLight® and MultiLight™, are used for the removal of unwanted hair from all skin types.

(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 K994014

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

(Optional Format 1-2-96)