FEB 4 1999

K 982119

510(K) PREMARKET NOTIFICATION
Diode Laser System
ESC Medical Systems Ltd.

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
Date summary prepared:	January 31, 1999
Device Trade Name:	ESC Diode Laser System
Common name:	Diode Laser
Classification name:	Laser instrument, powered, surgical (class II medical device)
Equivalent Devices:	AOC Laser Care System StarLight™ Laser System LaserLite Diode Surgical Laser System
Device Description:	The ESC Diode Laser System is a semiconductor diode laser system operating at the 830nm wavelength
Intended Use:	The ESC Diode Laser System is intended for the treatment of vascular and pigmented lesions including leg veins.
Comparison:	ESC Diode Laser System is comparable to its predicate devices in terms of the technical specifications, operating performance features, general physical configuration and intended uses. The energy delivered to the tissue is in the range of energy values delivered by the predicate devices.
Performance Standards:	The ESC Diode Laser System conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.
Conclusion:	The ESC Diode Laser System is substantially equivalent to other diode laser systems in commercial distribution for similar applications
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 4 1999

Dr. Zvi Ladin
Vice President
Clinical Applications and Regulatory Affairs
ESC Medical Systems Ltd.
Yokneam Industrial Park
P.O. Box 240
Yokneam 20692, Israel

Re: K982119
Trade Name: Diode Laser
Regulatory Class: II
Product Code: GEX
Dated: November 3, 1998
Received: November 6, 1998

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 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): K 982119

Device Name: ESC Diode Laser System

Indications For Use:

The ESC Diode Laser System is intended for the treatment of vascular and pigmented lesions including leg veins.

(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 K 982119
510(k) Number

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

(Optional Format 1-2-96)