APR 15 1998

K 980537

510(K) PREMARKET NOTIFICATION
PhotoDerm® Nd:YAG Accessory
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:	February 5, 1998
Device Trade Name:	PhotoDerm® Nd:YAG Accessory
Common name:	Nd:YAG Laser
Classification name:	Laser instrument, powered, surgical (class II medical device)
Equivalent Devices:	Sharplan 3100 Nd:YAG Laser System Laserscope Orion Laser System
Device Description:	The Nd:YAG laser accessory is a pulsed medical laser operating at a wavelength of 1064 nanometers. The device is operated by the PhotoDerm® system and emits high energy pulses of 1- 10 ms duration and up to 150 j/cm^2. The Nd:YAG laser accessory is a hand held device that replaces the standard optical treatment head used in the PhotoDerm® machines.
Intended Use:	Coagulation and hemostasis of pigmented vascular lesion and soft tissue
Comparison:	PhotoDerm® Nd:YAG Accessory 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 PhotoDerm® Nd:YAG Accessory conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.
Conclusion:	The PhotoDerm® Nd:YAG Accessory is substantially equivalent to other Nd:YAG 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

APR 15 1998

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

Re: K980537
Trade Name: PhotoDerm® Nd:YAG Accessory
Regulatory Class: II
Product Code: GEX
Dated: February 5, 1998
Received: February 11, 1998

Dear Dr. Ladin:

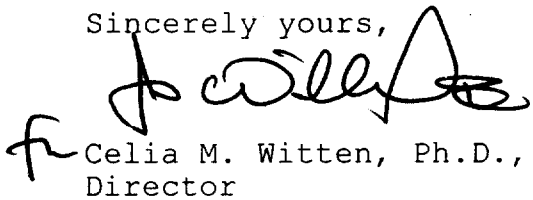
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K980537

Device Name: Nd:YAG accessory for PhotoDerm®

Indications For Use:

The PhotoDerm® Nd:YAG accessory is intended for coagulation and hemostasis of vascular lesions and soft tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980537

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

(Optional Format 1-2-96)