4. 510(K) SUMMARY

K972872

OCT 28 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter's name, address, telephone, fax, & contact person

Dr. Zvi Ladin
ESC Medical Systems Limited
Title: Vice President, Clinical Applications and Regulatory Affairs
Phone: 011-972-959-9000
Fax: 011-972-959-9050
Address: Yokneam Industrial Park, PO Box 240, Yokneam 20692, Israel

2. Date summary prepared:

July 31, 1997

3. Product trade or proprietary name:
Derma™ K laser system

4. Product common name:
Dual wavelength Er:YAG and CO_2 Laser System

5. Product classification name
21C.F.R. § 878.4810 Lasers in general and plastic surgery and in dermatology
21C.F.R. § 874.4500 Lasers for use in ENT
21C.F.R. § 884.4550 Gynecologic surgical laser

6. Legally marketed predicates device used for equivalency:

ESC Topaz™ 30 Laser System (K965015)
ESC Derma™ 20 Laser System (K964253)

7. Description:

The Derma™ K is a surgical laser system that produces laser (infrared) energy at wavelengths of 2.94 and 10.6 microns which is directed to soft tissue through an articulated arm system with removable handpieces.

8. Statement of intended use:

The intended use of the Derma™ K is drawn from that of the predicates Derma™ 20 and Topaz™ 30, namely the vaporization, incision, excision, ablation, or photocoagulation of soft tissue in the listed surgical specialties of:

- Dermatology
- Cosmetic Surgery
- Plastic and General Surgery
- Dental and Oral Surgery
- Gynecology
- Orthopedic
- Otorhinolaryngology (ENT)
- Podiatry

9. Clinical and Non-clinical Performance Data

None submitted.

10. Technological characteristics:

The Er:YAG laser output characteristics of the Derma™ K system and the predicate Derma™ 20 system are identical in average power, increments of power available, and wavelength. The electronic control systems, safety systems, cooling systems, Er:YAG laser, and aiming beam diode laser are identical.

The CO_2 laser output characteristics of the Derma™ K system and the predicate ESC Topaz™ 30 system are similar in average power, increments of power available, and wavelength. The laser and power source are identical in construction.

There are no technological characteristics of the Derma™ K that are different from the predicates.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients or operators due to operator error or in high risk procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1997

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

Re: K972872
Trade Name: DERMA™ K Laser System
Regulatory Class: II
Product Code: GEX
Dated: July 31, 1997
Received: August 4, 1997

Dear Dr. Ladin:

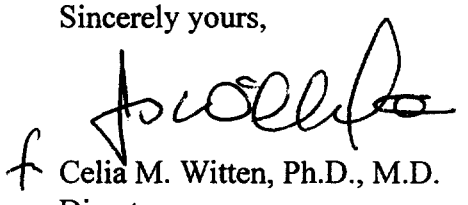
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

K972872

510(k) Number (if known):

Device Name: Derma™ K Laser System

Indications For Use:

The Derma™ K laser system is intended for incision, excision, ablation, vaporization and hemostasis of soft tissue.

(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 K972872

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

(Optional Format 1-2-96)