

**510(K) PREMARKET NOTIFICATION**

DermaScan™ Surgical Laser Scanner

ESC Medical Systems Ltd.

K978028

OCT 24 1997

**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:** May 29, 1997

**Device Trade Name:** DermaScan™ Surgical Laser Scanner

**Common name:** Laser Accessory

**Classification name:** Class II

**Equivalent Devices:**

- Sahar Technologies SofTouch Laser Accessory, 510(k) #K964684
- Clinicon Surescan Laser Scanner, 510(k) #K962242

**Device Description:** DermaScan™ Surgical Laser Scanner is a microprocessor controlled device that converts a surgical laser device into an advanced aesthetic surgery tool for a variety of cosmetic procedures. The device uses motorized mirrors to deflect a laser beam over a specified area in a uniform and controlled manner. Using a sophisticated interface the user can specify a large number of parameters to achieve a scanning procedure that is tailored to the individual needs of the patient. The scanner then controls the actual tissue ablation process to achieve a uniform removal of tissue over the entire area. An aiming beam is used to outline the treated area

**Intended Use:** Ablation of soft tissue

**Comparison:** DermaScan™ uses the same basic technology as the predicate devices. It offers added versatility to the scan parameters that are offered by the predicate devices. It also offers a larger and more versatile display that improves the human interface, and adds new safety features.

**Nonclinical Performance Data:** None

**Clinical Performance Data:** None

**Conclusion:** The DermaScan™ Surgical Laser Scanner is substantially equivalent to other laser scanners in commercial distribution for the same surgical application

**Additional Information** None requested at this time



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

OCT 24 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: K972028  
Trade Name: DermaScan™ Surgical Laser Scanner  
Regulatory Class: II  
Product Code: GEX  
Dated: September 3, 1997  
Received: September 12, 1997

Dear Dr. Ladin:

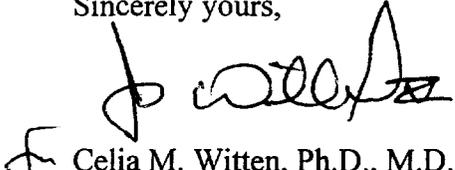
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



F 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): K972028

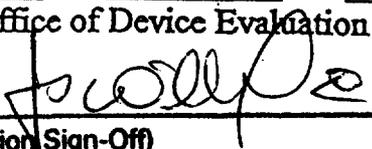
Device Name: DermaScan™ Surgical Laser Scanner

Indications For Use:

The DermaScan™ Surgical Laser Scanner is intended for use in soft tissue ablation procedures.

(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 K972028

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use