AUG - 9 1999

K991628

13.0 510(K) SUMMARY

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

   ESC Medical Systems
   Yokneam Industrial Park, PO Box 240, Yokneam 20692, Israel
   Phone: 972-4-959-9000 Fax: 972-4-959-9050
   Zvi Ladin, Vice President Clinical Applications and Regulatory Affairs

2. Date summary prepared:

   January 15, 1999

3. Product trade or proprietary name:

   Luxar modified LX-20 $C0_2$ Surgical Laser System

4. Product common name:

   $C0_2$ Laser

5. Product classification name

   21C.F.R. § 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology

   21C.F.R. § 874.4500 Ear, nose and throat microsurgical carbon dioxide laser

   21C.F.R. § 884.4550 Gynecologic surgical laser

6. Legally marketed predicate device used for equivalency:

   Luxar LX-20 $C0_2$ Surgical Laser System Family (K960475) and Sharplan 20C $C0_2$ Laser (K963229 and K935563).

7. Description:

   The Luxar modified LX-20 Surgical Laser System produces laser (infrared) energy at a wavelength of 10.6 microns which is directed to soft tissue through a knuckled beam delivery assembly, articulated arm or articulated arm plus hollow fiber waveguide, handpieces, and sterile delivery tips.

8. Statement of intended use:

The intended use of the modified LX-20 is identical to that of the LX-20 Laser System Family and the predicate Sharplan 20C, namely the vaporization, incision, excision, ablation, or photocoagulation of soft tissue in the listed surgical specialties of:

- Gynecology
- Laparoscopic Surgery Including GYN Laparoscopy
- Dermatology
- Dental and Oral surgery
- Orthopedic
- General Surgery
- Otorhinolaryngology
- Podiatry

The Modified LX-20 Laser has harmonized indications for use that are identical to the cleared LX-20 Laser System Family combined with the equivalent Sharplan 20C laser. There are no new indications for use beyond those cleared for the predicate devices, and no clinical data were presented.

9. Technological characteristics:

Basic system operation and performance are unchanged from the cleared LX-20 Laser System Family. The modified LX-20 and the cleared LX-20 Laser System Family share the same RF excited lasing tube, main chassis, power supply, safety systems, microprocessor controller, and much of the same electronics. The modified LX-20 laser system maintains the same 3 base consoles established pursuant to the predicate K960475 - namely the LX-20SI, the LX-20SP, the LX-20LP, and adds the fourth, the LX-20SA. The technological characteristics of the modified LX-20 that are different from the predicate LX-20 Laser System Family are as follows:

The modified unit adds the Sharplan articulated arm from the comparable Sharplan CO_2 laser. The articulated arm, used unchanged, allows the attachment of the Sharplan series of laser accessories. .

ESC believes that the minor differences in the delivery capabilities of the modified LX-20 and the LX-20 Laser System Family do not raise any new issues of safety and effectiveness.

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

AUG - 9 1999

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

Re: K991628
Trade Name: Luxar Modified LX-20 CO_2 Family of Surgical Lasers and Accessories
Regulatory Class: II
Product Code: GEX
Dated: May 9, 1999
Received: May 11, 1999

Dear Mr. Ladin:

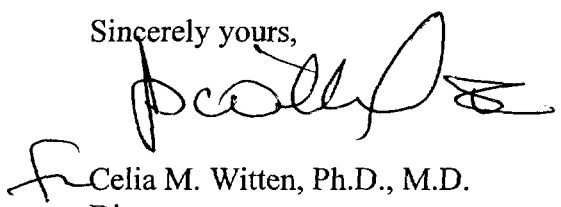
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Indications for Use - Dermatology

Representative examples: Tattoo removal; port wine hemangioma removal; rhinophyma reduction; telangiectasia removal; keloid reduction; wart removal; basal & squamous cell carcinoma removal; blepharoplasty; xanthalasma removal; removal of neurofibromas, hemangiomas, nevi, and tricoepitheliomas; dermabrasion such as for lentigos, keratoses, actinic keratosis & cheilitis.

Indications for Use - Dental/Oral Surgery

Representative examples: Gingivectomy; frenum release; removal of soft tissue, cysts, and tumors.

Indications for Use - Orthopedic

Representative examples: Menisectomy; chondromalacia ablation; partial synovectomy; lateral release; PMMA removal.

Indications for Use - General Surgery

Representative examples: Hemorrhoid removal; skin tag vaporization; pilodidal cyst removal and repair; debridement of decubitus ulcers and statis ulcers; mastectomy, breast biopsy, reduction mammoplasty; cytoreduction for metastatic disease; many dermatological procedures.

Indications for Use - Otorhinolaryngology (ENT)

Representative examples: Subglottic stenosis vaporization; tonsillectomy; removal of vocal cord papillomas, nodules, and polyps; lymphangioma removal; pulmonary bronchial and tracheal lesion removal; turbinectomy; removal of leukoplakia of larynx; ablation of choanal atresia. Myringotomy/tympanostomy; Laser Assisted Uvulopalatoplasty (LAUP).

Indications for Use - Podiatry

Representative examples: Plantar wart vaporization; fungal nail treatment; partial and complete matrixectomy; porokeratoma ablation; Morton's neruoma removal; ingrown nail treatment.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991628

Prescription Use K
(Per 21 CFR 801.109)

510(k) Number (if known): K991628

Device Name: LX-20 CO_2 Laser System Family

Indications for Use:

Intended Use

The modified LX-20 Laser System Family is a general surgical instrument used to vaporize, incise, excise, ablate, or photo coagulate soft tissue in surgical procedures in the listed surgical specialties.

The system may be effectively utilized for those applications recognized as within the accepted indications for use of $C0_2$ laser devices performed within the listed specialties and which require power densities as calculated by power and spot size referenced in the power density charts in the operator's manual.

Indications for Use - Gynecology

Representative examples: Condyloma, excision and vaporization, cervical, vulvar, & perineal; vaginal intraepithelial neoplasia ablation (VAIN); vulvar intraepithelial neoplasia ablation (VIN); herpes vaporization; urethral caruncle vaporization; I&D Bartholin's & nubothian cysts.

Indications for Use - Laparoscopic Surgery

Vaporization, incision, excision, ablation, or photo coagulation of soft tissue in endoscopic and laparoscopic surgery including GYN laparoscopy where delivery of energy by the hollow fiber may be more convenient than delivery of energy by a handpiece. Representative examples: endometriosis ablation; excision of adhesions; salpingotomy; metroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

on Sign-Off)
ion of General Restorative Devices
(K) Number K991628

Prescription Use X OR Over-The-Counter Use ___

(Per 21 CFR 801.109) (Optional Format 1-2-96)