K974996

MAR 27 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
LASERSCOPE EL LASER SYSTEM AND ACCESSORIES

REGULATORY AUTHORITY:
Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT:
~~Lisa McGrath~~ Paul H. Hardiman
Laserscope
3052 Orchard Drive
San Jose, CA 95134-2011
Phone: 408 943-0636
FAX: 408 943-1454

DEVICE TRADE NAME:
Laserscope EL Laser System and Accessories

DEVICE COMMON NAME:
Erbium:YAG Laser System

DEVICE DESCRIPTION:
The Laserscope EL Laser System and Accessories consists of a moveable console containing power supplies, aiming and treatment lasers on a solid optical deck, and a cooling mechanism to dissipate the heat generated by the system.

The entire laser unit and controls are contained in a single console. This console is electrically connected to the facility's power source. Emission of the laser beam is through an anodized aluminum articulated arm. The articulated arm is positioned at the left, upper part of the device and is not removable by the customer. Handpieces with removable, sterilizable tips, are available in 1, 3, 5 and 7 mm spotsizes.

The user interface consists of an LCD which displays laser parameters, data on connected devices and information on messages and prompts. Located on the front panel are four knobs enabling the user to select laser settings, and a READY/STANDBY button for selecting READY or STANDBY mode. An on/off keyswitch turns the laser system on and off. An emergency shut off button disables the laser and places the laser system in a holding status.

SUMMARY OF SAFETY AND EFFECTIVENESS,
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DEVICE CLASSIFICATION:
Erbium:YAG Laser Systems and Accessories have not been specifically classified; however Nd:YAG, CO_2, and Argon Surgical Lasers have been classified as Class II medical devices by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels.

PERFORMANCE STANDARDS:
The Laserscope EL Surgical Laser System and Accessories conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

INDICATION FOR USE STATEMENT:
The Laserscope EL Laser System and Accessories is indicated for use in procedures involving cutting (incision/excision), vaporizing, ablation and coagulation of soft tissue.

All soft tissue is included such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Clinical Applications:

Dermatology/Plastic Surgery
General Surgery
Genitourinary
Gynecology
Oral and Maxillofacial
Otorhinolaryngology/Head and Neck (ENT)
Ophthalmology
Podiatry

COMPARISON WITH PREDICATE DEVICE:
The Laserscope EL Laser System and Accessories is substantially equivalent to the Laserscope Erbium:YAG Laser System and Accessories, the Continuum Biomedical CB Erbium/2.94™ Erbium:YAG Laser, the Schwartz Electro-Optics, Inc. CLR 2940 Erbium CrystaLase, and the Coherent UltraFine™ Erbium Laser.

The risks and benefits for the Laserscope EL Laser System and Accessories are comparable to the predicate devices when used for similar clinical applications.

Since the Laserscope EL Laser System and Accessories is substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, we believe it clearly meets the requirements for substantial equivalence according to Section 510(k) guidelines. Safety and effectiveness are reasonably assured, therefore justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 1998

Mr. Paul H. Hardiman
Manager
Regulatory Affairs/Clinical Affairs
Laserscope
3052 Orchard Drive
San Jose, California 95134-2011

Re: K974896
Trade Name: Laserscope EL Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: December 29, 1997
Received: December 31, 1997

Dear Mr. Hardiman:

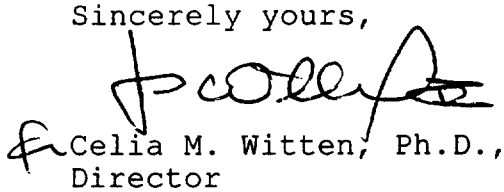
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 STATEMENT
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510(k) Number: K974896

Device Name: Laserscope EL Laser System and Accessories

Indications for Use:

The Laserscope EL Laser System and Accessories are intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as, skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Dermatology/Plastic Surgery: Indications include epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors and cysts, skin resurfacing, superficial skin lesions, and performing diagnostic biopsies.

General Surgery: Indications include surgical incision/excision, vaporization, ablation and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

Genitourinary: Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.

Gynecology: Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma

Oral/Maxillofacial: Indications include benign oral tumors, oral and glossal lesions and gingivectomy.

Otorhinolaryngology/Head and Neck (ENT): Indications include ear, nose and throat lesions, polyps, cysts, hyperkeratosis; excision of carcinogenic tissue and oral leukoplakia.

Ophthalmology: Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

Podiatry: Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use
(per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974896