

K970948

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
LASERSCOPE 800 SERIES SURGICAL LASER SYSTEM
(KTP UPGRADE) AND ACCESSORIES**

REGULATORY AUTHORITY

Safe Medical Device Act of 1990, 21 CFR 807.92

MAY 21 1997

COMPANY NAME/CONTACT:

Lisa McGrath
Laserscope
3052 Orchard Drive
San Jose, CA 95134
Phone: 408 943-0636
FAX: 408-943-1454

DEVICE TRADE NAME:

800 Series Surgical Laser System and Accessories

DEVICE COMMON NAME:

Laser Instrument, Surgical, Powered

DEVICE DESCRIPTION:

The Laserscope 800 Series Surgical Laser System is currently available in 8 configurations, 7 which have a KTP laser emitting light at 532 nm. This is achieved by passing the infrared beam produced by the Nd:YAG source through a second crystal made from potassium titanyl phosphate (KTP). The process that converts the infrared light to the visible green light requires two photons of infrared light to produce one photon of green light. This conversion process halves the wavelength, or doubles the frequency, so the wavelength of the KTP beam is exactly half that of the Nd:YAG beam.

The Laserscope 800 Series Surgical Laser System (KTP Upgrade) is achieved by an upgraded, higher quality q-switch and driver; increasing the power supply; adding a water to water heat exchanger and utilizing silicone based titanium dioxide lamp reflectors. Four new configurations are available:

Model 833, 2XP:	50 watts KTP/532, 100 watts Nd:YAG/1064, Dual Port
Model 834, 2XP:	50 watts KTP/532, 100 watts Nd:YAG/1064, Single Port
Model 843, 3XP:	60 watts KTP/532, 100 watts Nd:YAG/1064, Dual Port
Model 843, 3XP:	60 watts KTP/532, 100 watts Nd:YAG/1064, Single Port

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**SUMMARY OF SAFETY AND EFFECTIVENESS,
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DEVICE CLASSIFICATION:

The 800 Series Surgical Laser System (KTP Upgrade) and Accessories has been classified as a Class II medical device by the OB/GYN, General, Plastic Surgery and ENT Device Advisory Panels.

PERFORMANCE STANDARDS:

The 800 Series Surgical Laser System (KTP Upgrade) and Accessories conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

INDICATIONS FOR USE STATEMENT:

The 800 Series Surgical Laser System (KTP Upgrade) and Accessories is intended to be used for all currently cleared Laserscope indications. These indications include applications in the following specialities:

KTP/532 nm Applications: Dermatology, Gastroenterology, General Surgery, Gynecology, Head and Neck/Otorhinolaryngology (ENT), Neurosurgery, Ophthalmology, Spinal Surgery, Plastic Surgery, Thoracic Surgery and Urology.

COMPARISON WITH PREDICATE DEVICE:

The 800 Series Surgical Laser System (KTP Upgrade) and Accessories is substantially equivalent to the Laserscope 800 Series Surgical Laser System and Accessories.

The risks and benefits for the 800 Series Surgical Laser System (KTP Upgrade) and Accessories are comparable to the predicate device when used for similar clinical applications.

Since the 800 Series Surgical Laser System (KTP Upgrade) 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.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1997

Ms. Lisa McGrath
Senior Regulatory Affairs Specialist
Laserscope
3052 Orchard Drive
San Jose, California 95134-2011

Re: K970948
Trade Name: 800 Series Surgical Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: March 13, 1997
Received: March 14, 1997

Dear Ms. McGrath:

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.

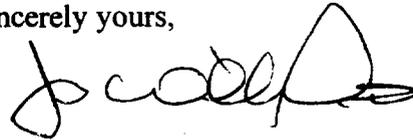
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Page 2 - Ms. Lisa McGrath

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

510(K) Number: 970948

Device Name: 800 Series Surgical Laser System (KTP/532, KTP/532 and Nd:YAG/1064 and Nd:YAG/1064 Configurations) and Accessories

Indications for Use: The 800 Series Surgical Laser System and Accessories is intended to be used for the following indications:

KTP/532 nm Applications:

Dermatology - indications include photocoagulation, hemostasis, color lightening, blanching flattening and reduction of lesion size for the following categories of lesions: vascular lesions including angiomas, hemangiomas, telangiectasia; benign pigmented lesions including nevi, lentigines, chloasma, cafe-au-lait, tattoos; cutaneous lesions including verrucae, skin tags, keratoses and plaques.

Gastroenterology - indications for hemostasis in the gastrointestinal tract including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers and gastric erosions. Indications for tissue ablation in the gastrointestinal tract including benign and malignant neoplasms, angiodysplasia, polyps, ulcers, colitis and hemorrhoids. Indications for esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma.

General Surgery - indications include vaporization, coagulation, incision, excision, debulking and ablation of soft tissue in endoscopic or open procedures.

Gynecology - indications include vaporization, incision and coagulation of tissue associated with treatments for conditions such as endometriosis; cervical, vulvar and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions and submucosal fibroids.

Head and Neck/Otorhinolaryngology (ENT) - indications include tissue incision, excision ablation and vessel hemostasis.

Neurosurgery - indications include incision, excision, coagulation and vaporization, of neurosurgical tumors of the firm, textured type.

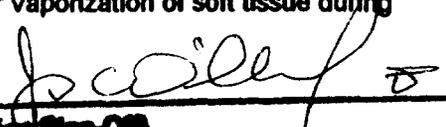
Ophthalmology - indications include post-vitreotomy endophotocoagulation of the retina.

Plastic Surgery - indications include vaporization, coagulation, incision, excision, debulking and ablation of soft tissue in endoscopic and open procedures.

Spinal Surgery - indications include percutaneous lumbar discectomy.

Thoracic Surgery - indications include vaporization, coagulation, incision, excision, debulking and ablation of soft tissue, including lung tissue in thoracoscopic or open procedures.

Urology - indications include cutting, coagulation or vaporization of soft tissue during urologic procedures.



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 970948

Indications for Use Statement,
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Nd:YAG/1064 Applications:

Dermatology - indications include photocoagulation of pigmented vascular lesions to reduce lesion size; for patients with lesions that would potentially benefit from aggressive treatment; and for patients with lesions that have not responded to other laser treatments.

Gastroenterology - indications for hemostasis in the gastrointestinal tract, including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers and gastric erosions. Indications for tissue ablation in the gastrointestinal tract including benign and malignant neoplasms, angiodysplasia, polyps, ulcers, colitis and hemorrhoids. Indications for esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma.

General Surgery - indications include cutting, ablation and/or hemostasis of soft tissue in endoscopic/laparoscopic and open general surgical applications, including cholecystectomy, appendectomy, vagotomy and pyloromyotomy. Soft tissue general surgical indications include skin incision, tissue dissection, excision of external tumors and lesions, tissue ablation, vessel coagulation and complete or partial resection of internal organs, tumors and lesions.

Gynecology - indications include treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus; ablation of endometrial implants and/or peritoneal adhesions; soft tissue excisional procedures, such as excisional conization of the cervix; intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated, including submucous fibroids, benign endometrial polyps and uterine septum.

Head and Neck/Otorhinolaryngology (ENT) - indications include tissue incision, excision, ablation and vessel hemostasis.

Hemostasis During Surgery - indications include adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic and open procedures.

Neurosurgery - indications include hemostasis for pituitary tumor, meningioma, hemoglioblastoma, AVMs, glioma, glioblastoma, astrocytoma and oligodendroglioma.

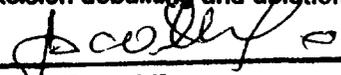
Oculoplastics - indications include incision, excision, vaporization and/or coagulation of tissue in oculoplastic procedures such as operations on the lacrimal system, operations on the eyelids, removal or biopsy of orbital tumors, enucleation of eyeball, exenteration of orbital contents.

Orthopedics - indications include cutting, ablation and/or hemostasis of intra-articular tissue in orthopedic surgical and arthroscopic applications.

Plastic Surgery - indications include cutting, incision, excision, coagulation and vaporization of soft tissue.

Pulmonary Surgery - indications include palliative procedures for benign and malignant pulmonary airway obstructions, including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, tracheal stenosis and benign strictures.

Thoracic Surgery - indications include cutting, incision, excision, coagulation and vaporization of soft tissue. Thoracic applications, including isolation of vessels for endarterectomy and/or bypass grafts, wedge resections, thoracotomy, formation of pacemaker pockets, vaporization, coagulation, incision, excision debulking and ablation of lung tissue (thoracoscopy).



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510(k) Number _____

Indications for Use Statement,
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Urology - indications include superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, bladder neck contracture, diverticulum and lesions of the external genitalia (including condyloma acuminata).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)
Division of General Restorative Devices 420948
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Prescription Use X
(per 21 CFR 801.109)

or Over-The-Counter Use