

K972575

JUL 17 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
LASERSCOPE KTP/Nd:YAG SURGICAL LASER SYSTEM
AND ANGLED DELIVERY DEVICES FOR THE TREATMENT OF BPH

REGULATORY AUTHORITY

Safe Medical Device Act of 1990, 21 CFR 807.92

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
Orion Series Surgical Laser System
Angled Delivery Devices (ADD Family Product Line)

DEVICE COMMON NAME:

Laser Instrument, Surgical, Powered
Laser Fiberoptic

DEVICE DESCRIPTION:

The Laserscope KTP/Nd:YAG Surgical Laser Systems lasing medium is an yttrium aluminum garnet (YAG rod) that has been doped with a small amount of the element neodymium (Nd). In this system, the electrons of the Nd atoms become excited and release photons of a characteristic wavelength. The light energy that is emitted from this source has a wavelength of 1064 nm which is in the infrared portion of the spectrum.

The KTP/532 laser utilizes the same lasing medium as the Nd:YAG laser. In this system, the infrared beam produced by Nd:YAG source is passed through a second crystal made from potassium titanyl phosphate (KTP). The KTP crystal converts some of the infrared light to visible light in the green portion of the spectrum. The wavelength of this light is 532 nm. 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. Thus, KTP is not a laser crystal, rather it is a frequency doubling crystal.

Laserscope's line of Angled Delivery Devices have side-firing capabilities for use in contact and non-contact procedures. The devices come in a variety of configurations (length, fiber core diameters, coaxial capability, etc.). The devices are available with either a Laserscope proprietary SmartConnector or a standard SMA-905 connector, facilitating use with either Laserscope or SMA-905 compatible lasers. The SmartConnector versions can transmit both the 532 and 1064 wavelengths.

**SUMMARY OF SAFETY AND EFFECTIVENESS,
PAGE 2**

DEVICE CLASSIFICATION:

Laserscope KTP/Nd:YAG Surgical Laser Systems have been specifically classified as Class II medical devices by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels. Laser fiberoptics have not been classified.

PERFORMANCE STANDARDS:

The Laserscope KTP/Nd:YAG Surgical Laser Systems conform with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

INDICATIONS FOR USE STATEMENT:

KTP/532 with Nd:YAG/1064:

Benign Prostatic Hyperplasia (BPH) - treatment for benign prostatic hyperplasia, intended for use in cutting, coagulating and vaporizing prostatic tissues during treatment of benign prostatic hyperplasia (BPH) in men 50 years of age or older with prostatic volumes of 60cc or less. Ablation and hemostasis are performed with Nd:YAG wavelength (1064 nm). Vaporization is performed with the KTP wavelength (532 nm). Specific indications include: laser prostatectomy, visual laser ablation of the prostate (VLAP), obstructive voiding symptoms, obstructive prostatic adenoma, prostatic enlargement, prostatic adenoma and bladder outlet obstruction due to BPH. The device is not intended to treat prostate cancer.

COMPARISON WITH PREDICATE DEVICE:

The Laserscope KTP/Nd:YAG Surgical Laser Systems and Angled Delivery Devices are substantially equivalent to the devices cleared under K912538, K933880, K920589 and K924644.

The risks and benefits for the Laserscope KTP/Nd:YAG Surgical Laser Systems and Angled Delivery Devices are comparable to the predicate devices when used for similar clinical applications.

Since the Laserscope KTP/Nd:YAG Surgical Laser Systems and Angled Delivery Devices are substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, we believe they clearly meet 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.



JUL 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K972575
Trade Name: 800 Series Surgical Laser System
Orion Series Surgical Laser System
Angled Delivery Devices (ADD Family Product Line)
Regulatory Class: II
Product Code: GEX
Dated: April 10, 1998
Received: April 14, 1998

Dear Mr. Hardiman:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

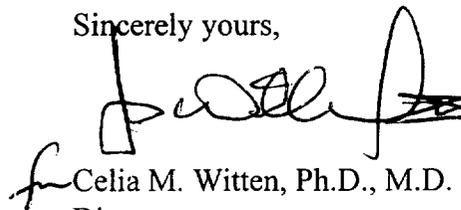
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

K 872575

INDICATIONS FOR USE STATEMENT

510(k) Number:

None assigned as of this time

Device Name:

800 Series Surgical Laser Systems and Accessories

Indications for Use:

The 800 Series Surgical Laser Systems and Accessories are intended for use in cutting, coagulating and vaporizing prostatic tissues during treatment of benign prostatic hyperplasia (BPH) in men 50 years of age or older with prostatic volumes of 60cc or less. Ablation and hemostasis are performed with Nd:YAG wavelength (1064 nm). Vaporization is performed with the KTP wavelength (532 nm). Specific indications include: laser prostatectomy, visual laser ablation of the prostate (VLAP), obstructive voiding symptoms, obstructive prostatic adenoma, prostatic enlargement, prostatic adenoma and bladder outlet obstruction due to BPH. The device is not intended to treat prostate cancer.

Concurrence of CDRH, Office of Device Evaluation (ODE)

- Prescription Use (per 21 CFR 801.109)
- Over-the-Counter Use



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982575

