K 964818

JUN 17 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
LASERSCOPE ORION SERIES SURGICAL LASER SYSTEM

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:

Orion Series Surgical Laser System

DEVICE COMMON NAME:

Laser Instrument, Surgical, Powered

DEVICE DESCRIPTION:

The Orion Series Surgical Laser System consists of a movable console containing power supplies, a treatment laser on a solid optical deck, and a cooling system to dissipate the heat generated by the system. A keypad control panel with CRT enables the user to control the laser system operating parameters.

Surgical power is controlled via a footswitch. Laser power is emitted only when the footswitch is depressed. The delivery system is through fiber optics.

Five configurations are currently available:

12W KTP only, 208 VAC
12W KTP/30W Nd:YAG, 208 VAC
20W KTP only, 208 VAC
20W KTP/50W Nd:YAG,208 VAC
50W Nd:YAG only, 208 VAC

DEVICE CLASSIFICATION:

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

PERFORMANCE STANDARDS:

The Orion Series Surgical Laser System conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

INDICATIONS FOR USE STATEMENT:

The Orion Series Surgical Laser System (Q-switched Nd:YAG configuration) is indicated for removal of dark tattoo ink, including blue and black.

COMPARISON WITH PREDICATE DEVICE:

The Orion Series Surgical Laser System (Q-switched Nd:YAG configuration) is substantially equivalent to the Medlite™ Q-switched Nd:YAG Laser System, manufactured by Continuum Biomedical, Inc.

The risks and benefits for the Orion Series Surgical Laser System are comparable to the predicate device when used for similar clinical applications.

Since the Orion Series Surgical Laser System (Q-switched Nd:YAG configuration) 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

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

JUN 17 1997

Re: K964818
Trade Name: Orion Series Surgical Laser System (Q-switched Nd:YAG configuration)
Regulatory Class: II
Product Code: GEX
Dated: March 18, 1997
Received: March 19, 1997

Dear Ms. McGrath:

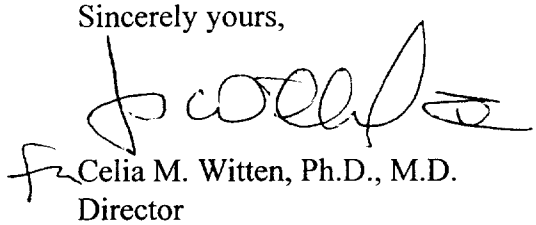
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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: K964818

Device Name: **Orion Series Surgical Laser System (Q-switched Nd:YAG configuration)**

Indications for Use:

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(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 K964818

Prescription Use X
(per 21 CFR 801.109)

or

Over-The-Counter Use