

K971250

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**  
**LASERSCOPE MICROBEAM IV MICROMANIPULATOR**

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

JUN 30 1997

**COMPANY NAME/CONTACT:**

Lisa McGrath  
Laserscope  
3052 Orchard Drive  
San Jose, CA 95134-2011  
Phone: 408 943-0636  
FAX: 408 943-1454

**DEVICE TRADE NAME:**

Laserscope Microbeam IV Micromanipulator

**DEVICE COMMON NAME:**

Microbeam IV Micromanipulator

**DEVICE DESCRIPTION:**

The Laserscope Microbeam IV is a micromanipulator that delivers KTP/532 laser energy to a very localized area. The Microbeam IV is used in conjunction with a microscope that allows the surgeon to accurately position the laser; the Microbeam IV can produce a spot size from 250 microns to 400 microns.

The Microbeam IV system consists of an optical assembly which focuses the laser light from the fiber optic cable to the surgical site. The Microbeam IV delivers the laser energy in line with the viewing path. There are two focusing adjustments on the Microbeam IV; the fine focus and the rapid defocus. The fine focus adjustment is used to focus the laser beam at the tissue. The rapid defocus knob quickly increases the laser spot size at the tissue. The Microbeam IV is compatible with most microscopes and can be used with most objective lenses.

**SUMMARY OF SAFETY AND EFFECTIVENESS,  
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**DEVICE CLASSIFICATION:**

To the best of our knowledge, Microbeam IV Micromanipulators have not been specifically classified; however, the surgical lasers for which they are intended have been classified as Class II medical devices by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels.

**PERFORMANCE STANDARDS:**

The Laserscope KTP/532 and KTP/YAG Surgical Laser Systems conform with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems. Laserscope is unaware of any specific standards for micromanipulators.

**INDICATION FOR USE STATEMENT:**

The Laserscope Microbeam IV Micromanipulator is intended to be used in conjunction with a microscope for all cleared Laserscope indications for the KTP/532 and KTP/YAG Surgical Laser Systems.

**COMPARISON WITH PREDICATE DEVICE:**

In the opinion of Laserscope, the Laserscope Microbeam IV is substantially equivalent to the existing family of Laserscope Microbeam Micromanipulators. The risks and benefits for the Laserscope Microbeam IV Micromanipulator are comparable to the predicate device when used for similar clinical applications.

Since the Laserscope Microbeam IV Micromanipulator 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

JUN 30 1997

Re: K971250  
Trade Name: Laserscope Microbeam IV Micromanipulator  
Regulatory Class: II  
Product Code: GEX  
Dated: March 31, 1997  
Received: April 1, 1997

Dear Ms. McGrath:

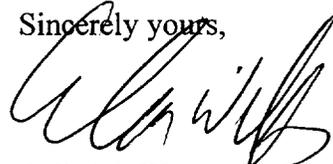
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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. 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:           K971250          

Device Name: Laserscope Microbeam IV Micromanipulator

Indications for Use: The Laserscope MicroBeam IV Micromanipulator is a .....  
micromanipulator that delivers KTP/532 Laser energy to a very  
localized area.

The Laserscope Microbeam IV Micromanipulator is intended to  
be used in conjunction with a microscope for all  
cleared Laserscope indications for the KTP/532 and  
KTP/YAG Surgical Laser Systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Prescription Use \_\_\_\_\_  
(per 21 CFR 801.109)

or

Over-The-Counter Use

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

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