NOV 18 1998

K984110

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:

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Manager, Regulatory Affairs/Clinical Affairs
Laserscope
3052 Orchard Drive
San Jose, CA 95134-2011
Phone: 408 943-0636
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DEVICE TRADE NAME:

Laserscope CoolSpot™

DEVICE COMMON NAME:

COOLING DEVICE

DEVICE DESCRIPTION:

The CoolSpot™ is essentially a "heat sink" which works by utilizing the latent heat of fusion properties of water and the thermal conductivity of copper and sapphire. The device design consists of a handpiece and a removable sealed reservoir of water that is frozen prior to use. The CoolSpot™ handpiece will house the cool tip and the laser delivery device during use. The cool tips will be stored in a freezer when not in use. A storage rack will be provided to hold up to 4 cool tips.

SUMMARY OF SAFETY AND EFFECTIVENESS,
(PAGE 2)

The "active component", the cool tip, consists of a sealed tube filled with water that has a sapphire window affixed to its distal end. The tube is made of copper, which is gold plated and coated in plastic. The CoolSpot™ handpiece is designed so a laser delivery device is positioned such that the treatment beam passes through a sapphire window, which is cooled by virtue of its contact with the tubing and ice/water reservoir. The sapphire window will be in physical contact with the target treatment area during active use. The primary purpose of the window is to provide a heat sink in contact with the skin, which is at a lower temperature than the average skin surface temperature. The sapphire window will initially cool the skin and during laser activation, will absorb a portion of the heat generated by the selective absorption of the laser energy by the skin.

DEVICE CLASSIFICATION:

Laser Surgical Instrument Accessory for use in General and Plastic Surgery and Dermatology

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.

SUMMARY OF SAFETY AND EFFECTIVENESS,
(PAGE 3)

INDICATION FOR USE STATEMENT:

To provide surface cooling effect during cutaneous laser surgery to minimize thermal injury to non-vascular skin structures during laser therapy of benign cutaneous vascular lesions, and to possibly reduce pain associated with laser treatment.

CLINICAL APPLICATIONS:

Cosmetic/Dermatology/Plastic Surgery with the following FDA 510(k) marketing

COMPARISON WITH PREDICATE DEVICE:

The Laserscope CoolSpot™ is substantially equivalent to the Cool Laser Optics device and to Cold Packs. The operating principle of these devices is topical application of a low-temperature material to the surface of the skin in order to reduce its temperature. The intended use of the devices are substantially equivalent in that they are intended to reduce pain and minimize thermal injury to non-vascualr skin structures during laser therapy of benign cutaneous lesions.

The risks and benefits for the Laserscope CoolSpot™ is comparable to the predicate devices when used for similar clinical applications.

SUMMARY OF SAFETY AND EFFECTIVENESS,
(PAGE 4)

Since the Laserscope CoolSpot™ is substantially equivalent with respect to indications for use, materials, and method of operation to the predicate devices, 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.

FDA 510(k) Cleared Devices:

Laserscope has received 510(k) clearances from FDA for its Lasers and Accessories intended to be used with Laserscope's CoolSpot™ as follows:

DL Laser Systems (AURA)
"SL" Series Surgical Laser Systems
(KTP/532,KTP Yag™ and ND:Yag™ /
1064 Configurations)
Orion Series Surgical Laser System
Q-Switched ND:Yag™ configuration
Laserscope's Microspot Dermastat
Q-Stat Handpiece

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

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

Re: K984110
Trade Name: Laserscope CoolSpot™
Regulatory Class: II
Product Code: GEX
Dated: November 12, 1998
Received: November 17, 1998

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
Page 1

510(k) Number: K984110

Device Name: CoolSpot™

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

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 K984110