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510(k) Summary Statement
For the Gemini™ G Surgical Laser System & Accessories

General Information

A. Trade Name
Gemini™ Series Surgical Laser System

B. Common Name
Laser Instrument, Surgical, Powered

C. Establishment Registration Number

2937094

D. Manufacturer's Identification

Laserscope
3070 Orchard Drive
San Jose, CA 95134-2011
(800) 243-9384-ext. 6795
(408) 943-9630 FAX

Official Correspondent
Paul Hardiman
Manager, Regulatory Affairs/Clinical Affairs

E. Device Classification

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

F. Performance Standards

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

G. Predicate Devices:

- Laserscope Lyra™ G Laser System and Accessories
- AURA *i*™ Surgical Laser System & Accessories
- Laserscope Lyra™ Laser System and Accessories

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H. Product Description:

The Laserscope Gemini™ Surgical Laser System and Accessories consists of four major subsystems:

- The Optical and Laser resonator System
- The Electronics and Electrical System
- Operator Interface
- A variety of Delivery Devices and Accessories
- A Cooling Sub-system

I. Indications For Use:

The Laserscope Gemini™ Laser System & Accessories is indicated for:

KTP/532 Applications:

Dermatology: To treat moderate inflamatory acne vulgaris;

ND:YAG/1064 Applications:

Dermatology: For use in the Dermatological Applications for the treatment of facial wrinkles. It is also intended to effect stable long-term, or permanent hair reduction in skin types I – VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term, stable, reduction in the number of hairs re-growing after a treatment regimen.

J. Rationale for Substantial Equivalence

The Laserscope Gemini Surgical Laser System and Accessories share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to: the Laserscope Lyra G Surgical Laser System and Accessories; the Laserscope Aura "DL" Series Surgical Laser Systems (KTP/532, KTP/YAG™ and Nd:YAG/1064 Configurations);and, the Laserscope Lyra Laser System and Accessories. Details are provided in the Substantial Equivalence Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2004

Mr. Paul H. Hardiman
Manager, Regulatory Affairs
Laserscope
3070 Orchard Drive
San Jose, California 95134

Re: K034011
Trade/Device Name: GEMINI™ Surgical Laser System & Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 22, 2003
Received: December 31, 2003

Dear Mr. Hardiman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: **K034011**

Device Name: GEMINI™ SURGICAL LASER SYSTEM & ACCESSORIES

INTENDED USE:

The Laserscope Gemini™ Laser System & Accessories is indicated for:

KTP/532 Applications:

Dermatology: To treat moderate inflammatory Acne vulgaris.

ND:YAG/1064 Applications:

Dermatology: For use in the Dermatological Applications for the treatment of facial wrinkles. It is also intended to effect stable long-term, or permanent hair reduction in skin types I – VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term, stable, reduction in the number of hairs re-growing after a treatment regimen.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over The-Counter-Use

(per 21 CFR 801.109)

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K034011