JUL - 2 2002

Laserscope
Lyra™ Surgical Laser System & Accessories
510(k) Premarket Notification

K020021

510(k) Summary

This 510(k) Summary of Safety & Effectiveness for the Laserscope's Lyra Surgical Laser System & Accessories is submitted in accordance with the requirements of SMDA 1990 and CFR 807.92 and CFR 807.93 follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

A. Trade Name
Lyra™ Surgical Laser System and Accessories (Nd:YAG configuration)

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
(408) 943-0636
(503) 961-1688 FAX

Official Correspondent
Paul Hardiman
Manager, Regulatory Affairs/Clinical Affairs

E. Device Classification
The Lyra™ 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 Lyra™ Series Surgical Laser System conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

G. Device Description
The Lyra™ Series Surgical Laser Systems are Nd:YAG lasers producing laser emission @ 1064nm. The Laserscope Lyra Surgical Laser System consists of four major subsystems:

The Optical and Laser Resonator system; The Cooling system; The Electronics and Electrical system; The Operator interface.

G. Substantial Equivalence
In the opinion of Laserscope, the Laserscope Lyra™ Surgical Laser System & Accessories is substantially equivalent in technology and intended use to the Lyra™ Surgical Laser System FDA cleared under 510(k) K9990903, the CoolTouch Nd:YAG Laser System FDA cleared under 510(k) K003715, and the SLS NLite System FDA cleared under 510(k) K000811.

H. Indications For Use:
The Laserscope Lyra™ Laser Systems & Accessories are indicated for use in the Dermatological applications for the treatment of facial wrinkles.

I. Nonclinical Performance Data:
None.

J. Clinical Performance Data:
Clinical studies produced results that indicate the Laserscope Lyra™ Laser Systems & Accessories is safe and effective for the treatment of facial wrinkles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Laserscope
Paul Hardiman
Manager, Regulatory Affairs/Clinical Affairs
3070 Orchard Drive
San Jose, California 95134-2011

Re: K020021
Trade Name: Lyra G™ Series Laser System and Accessories (Nd: YAG configuration)
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument, powered
Regulatory Class: II
Product Code: GEX
Dated: April 11, 2002
Received: April 12, 2002

Dear Mr. Hardiman:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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
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510(k) Number: K020021

Device Name: LASERSCOPE LYRA™ SERIES SURGICAL LASER SYSTEM & Accessories

Indications for Use: **The Laserscope Lyra™ Laser Systems & Accessories are indicated for use in the Dermatological applications for the treatment of facial wrinkles.**

(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
and Neurological Devices

510(k) Number K020021

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