

3/5/99

K984424

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY:

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT:

Paul H. Hardiman

Manager, Regulatory Affairs/Clinical Affairs

Laserscope

3052 Orchard Drive

San Jose, CA 95134-2011

Phone: 408 943-0636

FAX: 408 943-1454

DEVICE TRADE NAME:

Aura Dye Laser System (ADLS)

DEVICE COMMON NAME:

Tunable Dye Laser System

DEVICE DESCRIPTION:

The Laserscope Aura Dye Laser System and Accessories consists of a moveable consoles containing power supplies, aiming and treatment lasers on a solid optical deck, and a cooling mechanism to dissipate the heat generated by the system.

The entire laser unit and controls are contained in two consoles, an Aura KTP/532 laser as a pump source, and a Dye Module to produce treatment light. Consoles 1 and 2 are electrically connected to the facility's power

source. Emission of the pumping laser beam from Console 1 is through a flexible fiber optic to Console 2, the Dye Laser Module. Treatment light is delivered from Dye Module through fiber optic handpieces and/or scanner. The user interface consists of an LCD on Console 1 which displays laser parameters, data on connected devices and information on messages and prompts. Located on the front panel of Console 1 are four knobs enabling the user to select laser settings, and a READY/STANDBY button for selecting READY or STANDBY mode. An on/off keyswitch turns the laser system on and off. An emergency shut off button disables the laser and places the laser system in a holding status.

DEVICE CLASSIFICATION:

KTP/532 Pumped Dye Laser Systems and Accessories have not been specifically classified; however Nd:YAG, CO₂, and Argon Surgical Lasers have been classified as Class II medical devices by the OB/GYN, General Plastic Surgery and ENT Device Advisory Panels (884.4550, 878.4810, and 874.4490 & 874.4500, respectively)..

PERFORMANCE STANDARDS:

The Laserscope Aura Dye Laser System and accessories complies with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

INDICATION FOR USE STATEMENT:

The Laserscope Aura Dye Laser System and Accessories is indicated for use in the procedures involving cutting (incision/excision), vaporizing,

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ablation and coagulation of soft tissue.

All soft tissue is included such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

CLINICAL APPLICATIONS:

Dermatology / Plastic Surgery

General Surgery

Genitourinary

Gynecology

Oral / Maxillofacial

Otorhinolaryngology / Head and Neck (ENT)

Ophthalmology

Podiatry

COMPARISON WITH PREDICATE DEVICE:

The Laserscope Aura Dye Laser System is substantially equivalent to Laserscope Aura and Orion Lasers systems, as well as the Coherent Versa Pulse C, Candela ScleroPulse, and Cynosure PhotoGenica LV laser systems based on wavelength, pulse duration and/or pulse frequency.

The risks and benefits for the Laserscope Aura Dye Laser System and Accessories are comparable to the predicate devices when used for similar clinical applications.

Since the Laserscope Aura Dye Laser System and Accessories are



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.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

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

Re: K984424
Trade Name: Tunable Aura Dye Laser System
Regulatory Class: II
Product Code: GEX
Dated: December 10, 1998
Received: December 11, 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

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510(k) Number: K984424

Device Name: Tunable Aura Dye Laser System

Indications for Use:

The Laserscope Aura Dye Laser System and Accessories are intended for the surgical incision/excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Dermatology/Plastic Surgery: Indications include epidermal nevi, telangiectasia, spider veins, verrucae, skin tags, anal tags, keratoses, debulking benign tumors and cysts, superficial skin lesions, and benign pigmented lesions.

General Surgery: Indications include surgical incision/excision, vaporization, ablation and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablations and/or vessel coagulation may be indicated.

Genitourinary: Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.

Gynecology: Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts, and condyloma.

Oral/Maxillofacial: Indications include benign oral tumors, oral and glossal lesions.

Otorhinolaryngology/Head and Neck (ENT): Indications include ear, nose and throat lesions, polyps, cysts, excision of carcinogenic tissue and oral leukoplakia.

Ophthalmology: Indications include soft tissue surrounding the eye and orbit.

Podiatry: Indications include wart, plantar verrucae, and large mosaic verrucae.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: or Over-The-Counter-Use
(per 21 CFR 801.109)

Steph Plueck
(Division Sign-Off)
Division of General Restorative Devices K984424