

AUG 27 1999

K 990903

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS  
LASERSCOPE Lyra SURGICAL LASER SYSTEM

---

**REGULATORY AUTHORITY**

Safe Medical Device Act of 1990, 21 CFR 807.92

**COMPANY NAME/CONTACT:**

Paul Hardiman  
Laserscope  
3052 Orchard Drive  
San Jose, CA 95134  
Phone: 408-943-0636  
FAX: 408-934-1454

**DEVICE TRADE NAME**

Lyra Surgical Laser System & Accessories

**DEVICE COMMON NAME**

Laser Instrument, Surgical, Powered

**DEVICE DESCRIPTION:**

The LYRA Laser systems are intended to be semi-portable systems which target the office and small out-patient surgery markets. The laser output characteristics and fiber optical beam delivery method of these LYRA systems are very similar to the Laserscope "Orion" though physically they are much more similar to the Laserscope "Aura" systems. The LYRA systems are based on the same chassis, bezel and user interface as the "Aura" laser systems.

The LYRA Systems described herein are capable of delivering laser energy equivalent to the systems Laserscope currently has in commercial distribution and will operate in the following modes:

•1 to 50 Joule StarPulsed and StarPulsedQ 1.064 micron wavelength laser output at frequencies from single shot to 100 HZ.

**Summary of Safety and Effectiveness,  
Page 2**

**DEVICE CLASSIFICATION:**

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

**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.

**INDICATIONS FOR USE STATEMENT**

The LYRA Series Surgical 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.

**KTP/532 Applications**

**Dermatology:** Photocoagulation of cutaneous lesions including but not limited to the following general categories of lesions: Vascular lesions (Angiomas, Hemangiomas, Telangiectasia); Benign pigmented lesions (Nevi, Lentiginos, Chloasma, Café-au-lait, Tattoos (including but not limited to blue and black dark tattoo ink); Verrucae; Skin Tags; Keratoses; Plaques; Cutaneous Lesion Treatment (Hemostasis, Color Lightening, Blanching, Flattening, Reduction of lesion size).

**General Surgery:** Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

**Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Esophagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

**Summary of Safety and Effectiveness,**  
Page 3

**Gynecology:** Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepithelial neoplasia; Condyloma Acuminata; Uterine Septum; Intrauterine adhesions; Submucosal fibroids.

**Head and Neck/Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis.

**Neurosurgery:** Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

**Ophthalmology:** Post-vitrectomy endophotocoagulation of the retina.

**Plastic Surgery:** Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

**Spinal Surgery:** Percutaneous lumbar discectomy.

**Thoracic Surgery:** Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

**Urology:** Cutting, coagulating, or vaporizing urologic soft tissues.

**ND:YAG/1064 Applications**

**Dermatology:** Photocoagulation of pigmented lesions to reduce lesion size. For patients with lesions that would potentially benefit from aggressive treatment. For patients with lesions that have not responded to other laser treatments.

**Endoscopic/Laparoscopic General Surgery:** Cutting, ablation, and/or hemostasis of soft tissue in endoscopic or laparoscopic general surgery applications, including but not limited to: Cholecystectomy, Appendectomy, Vagotomy, Pyloromyotomy.

**Summary of Safety and Effectiveness,**  
**Page 4**

**Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions including Squamous cell carcinoma and Adenocarcinoma; Gastrointestinal hemostasis including: Varices, Esophagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal ulcers, non-bleeding ulcers, Gastric erosions; Gastrointestinal tissue ablation including: Benign and malignant neoplasm; Angiodysplasia; Polyps; Ulcer; Colitis; Hemorrhoids.

**General Surgery:** Soft tissue general surgery applications: Skin incision; Tissue dissection; Excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; Tissue ablation; Vessel Coagulation.

**Gynecology:** Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus; Ablation of endometrial implants and/or peritoneal adhesions; Soft tissue excisional procedures, such as excisional conization of the cervix; intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including Submucous fibroids, Benign endometrial polyps, Uterine septum.

**Head and Neck/Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis.

**Hemostasis during Surgery:** Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

**Neurosurgery:** Hemostasis for: Pituitary Tumor; Meningioma; Hemangioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

**Oculoplastics:** Incision, Excision, Vaporization and/or coagulation of tissues in Oculoplastic procedures such as: Operations on the lacrimal system; Operation on the eyelids; Removal of biopsy or orbital tumors; Enucleation on eyeball; Extenteration of orbital contents.

**Orthopedics:** Cutting, ablation, and/or hemostasis of intra-articular tissue in Orthopedic surgical and arthroscopic applications.

**Summary of Safety and Effectiveness,**  
Page 5

**Plastic Surgery:** Cutting (incision/excision), coagulating, and vaporizing of soft tissue.

**Pulmonary Surgery:** Palliative treatment of benign and malignant pulmonary airway obstructions, including: Squamous Cell Carcinoma; Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

**Thoracic Surgery:** Cutting (incision/excision), coagulating, and vaporizing of soft tissue. Thoracic applications including, but not limited to: Isolation of vessels for endarterectomy and/or by-pass grafts; Wedge Resections ; Thoractomy; Formation of Pacemaker pockets. Vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (Thoracoscopy).

**Urology:** All applications including: Superficial urinary bladder tumors; Invasive bladder carcinoma; Urethral Strictures; Lesions of the external genitalia (including condyloma acuminata).

**TECHNOLOGICAL CHARACTERISTICS**

The Lyra is substantially equivalent to Laserscope's Orion lasers which have 510(K) clearance for use on soft tissues

The Orion lasers manufactured by Laserscope have demonstrated the safety and efficacy of using pulsed 532 and 1064 nm light for cutting and coagulating soft tissue. These lasers emit pulsed light with the similar temporal characteristics (pulse durations and PPS), use the same delivery systems, and use similar power densities for treating soft tissue. As the wavelength of light is increased from 532 to 1064 nm the scattering and absorption coefficients of tissue decrease allowing the light to penetrate further into tissue. The limited penetration depth of 532 nm light in tissue makes it useful for cutting soft tissue and at lower fluences coagulating superficial blood vessels. The greater penetration depth of 1064 nm light on the other hand makes it more useful for coagulating soft tissue and large blood vessels.

**Summary of Safety and Effectiveness,  
Page 6**

**SUBSTANTIAL EQUIVALENCE DETERMINATION:**

Since the Lyra Series Surgical Laser System is substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device (Laserscope's ORION Surgical Laser System), we believe they clearly meet the requirements for substantial equivalence according to 510(k) guidelines. Safety and effectiveness are reasonable assured, therefore justifying 510(k) clearance.

**Lyra SPECIFICATIONS**

Laser type	ND:Yag
Laser Pump Source	Krypton Arc lamp
Wavelength	532nm/1064nm
TEM Mode	Multi-Mode
Maximum Energy per Pulse	50 Joules
Maximum Repetition rate	100 HZ
Pulse width	1-100 ms
Maximum Coupling NA	.22
Treatment Spot sizes	1-10 mm
Cooling System	Coolant to air heat exchanger
Display	LCD, Indicator lights
Operator Beam Control	Footswitch or Handswitch
Aim Beam	630-680 nm Laser Diode



AUG 27 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K990903  
Trade Name: Lyra Surgical Laser System and Accessories  
Regulatory Class: II  
Product Code: GEX  
Dated: June 20, 1999  
Received: June 22, 1999

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.

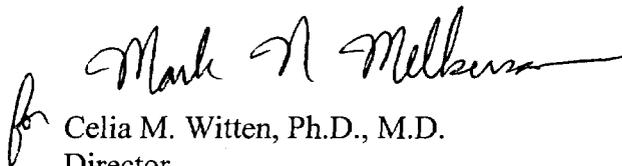
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Paul H. Hardiman

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,

for Mark A. Melkerson

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

*Mark N. Melburn*

for

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

K990903  
10F3

**INDICATIONS FOR USE STATEMENT**  
Page 1 of 3

510(k) Number: K990903 \_\_\_\_\_

Device Name: LYRA SERIES SURGICAL LASER SYSTEM & Accessories

**Indications for Use:**

The LYRA Series Surgical 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.

**KTP/532 Applications**

**Dermatology:** Photocoagulation of cutaneous lesions including but not limited to the following general categories of lesions: Vascular lesions (Angiomas, Hemangiomas, Telangiectasia); Benign pigmented lesions (Nevi, Lentigines, Chloasma, Café-au-lait, Tattoos (including but not limited to blue and black dark tattoo ink); Verrucae; Skin Tags; Keratoses; Plaques; Cutaneous Lesion Treatment (Hemostasis, Color Lightening, Blanching, Flattening, Reduction of lesion size).

**General Surgery:** Vaporizing, Coagulating, Incising, Excising, Debulking, and Ablating of Soft tissue as well as in Endoscopic (e.g. laparoscopic) or open surgeries.

**Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; Gastrointestinal hemostasis (including Varices, Esophagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal Ulcers, Non-bleeding Ulcers, Gastric erosions); Gastrointestinal Tissue ablation (Benign and Malignant neoplasm, Angiodysplasia, Polyps, Ulcer, Colitis, Hemorrhoids).

**Gynecology:** Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: Endometriosis; Cervical, vulvar, and vaginal intraepithelial neoplasia; Condyloma Acuminata; Uterine Septum; Intrauterine adhesions; Submucosal fibroids.

**Head and Neck/Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis.

**Neurosurgery:** Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

**Ophthalmology:** Post-vitrectomy endophotocoagulation of the retina.

**Plastic Surgery:** Vaporizing, Coagulating, Incising, Excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

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

X

*Mark A. Melkerson*

for

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K990903

20F3

INDICATIONS FOR USE STATEMENT

Page 2 of 3

510(k) Number:

K990903

Device Name: LYRA SERIES SURGICAL LASER SYSTEM & Accessories

**Spinal Surgery:** Percutaneous lumbar discectomy.

**Thoracic Surgery:** Vaporizing, Coagulating, Incising, Excising, Debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

**Urology:** Cutting, coagulating, or vaporizing urologic soft tissues.

ND:YAG/1064 Applications

**Dermatology:** Photocoagulation of pigmented lesions to reduce lesion size. For patients with lesions that would potentially benefit from aggressive treatment. For patients with lesions that have not responded to other laser treatments.

**Endoscopic/Laparoscopic General Surgery:** Cutting, ablation, and/or hemostasis of soft tissue in endoscopic or laparoscopic general surgery applications, including but not limited to: Cholecystectomy, Appendectomy, Vagotomy, Pyloromyotomy.

**Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; Esophageal neoplastic obstructions including Squamous cell carcinoma and Adenocarcinoma; Gastrointestinal hemostasis including: Varices, Esophagitis, Esophageal Ulcer, Mallory-Weiss tear, Gastric Ulcer, Angiodysplasia, Stomal ulcers, non-bleeding ulcers, Gastric erosions; Gastrointestinal tissue ablation including: Benign and malignant neoplasm; Angiodysplasia; Polyps; Ulcer; Colitis; Hemorrhoids.

**General Surgery:** Soft tissue general surgery applications: Skin incision; Tissue dissection; Excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; Tissue ablation; Vessel Coagulation.

**Gynecology:** Treatment of menorrhagia by photocoagulation of the endometrial lining of the uterus; Ablation of endometrial implants and/or peritoneal adhesions; Soft tissue excisional procedures, such as excisional conization of the cervix; intra-uterine gynecologic procedures where cutting, ablation and/or vessel coagulation may be indicated including Submucous fibroids, Benign endometrial polyps, Uterine septum.

**Head and Neck/Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis.

Prescription Use  
(Per 21 CFR 801.109)

X

*Mark N. Miller*

for (Division Sign-Off)  
Division of General Restorative Devices *K990903*  
510(k) Number \_\_\_\_\_  
*3 of 3*

INDICATIONS FOR USE STATEMENT

Page 3 of 3

510(k) Number:

*K990903*

Device Name: LYRA SERIES SURGICAL LASER SYSTEM & Accessories

**Hemostasis during Surgery:** Adjunctive coagulation and hemostasis (bleeding control) during surgery in endoscopic (e.g. laparoscopic) and open procedures.

**Neurosurgery:** Hemostasis for: Pituitary Tumor; Meningioma; Hemangioblastoma; AVMs; Glioma; Glioblastoma; Astrocytoma; Oligodendroglioma.

**Oculoplastics:** Incision, Excision, Vaporization and/or coagulation of tissues in Oculoplastic procedures such as: Operations on the lacrimal system; Operation on the eyelids; Removal of biopsy or orbital tumors; Enucleation on eyeball; Exteneration of orbital contents.

**Orthopedics:** Cutting, ablation, and/or hemostasis of intra-articular tissue in Orthopedic surgical and arthroscopic applications.

**Plastic Surgery:** Cutting (incision/excision), coagulating, and vaporizing of soft tissue.

**Pulmonary Surgery:** Palliative treatment of benign and malignant pulmonary airway obstructions, including: Squamous Cell Carcinoma; Adenocarcinoma; Carcinoid; Benign Tumors; Granulomas; Benign Strictures.

**Thoracic Surgery:** Cutting (incision/excision), coagulating, and vaporizing of soft tissue. Thoracic applications including, but not limited to: Isolation of vessels for endarterectomy and/or by-pass grafts; Wedge Resections ; Thoractomy; Formation of Pacemaker pockets. Vaporization, coagulation, incision/excision, debulking, and ablation of lung tissue (Thoracoscopy).

**Urology:** All applications including: Superficial urinary bladder tumors; Invasive bladder carcinoma; Urethral Strictures; Lesions of the external genitalia (including condyloma acuminata).

(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)