

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS  
LASERSCOPE ORION SERIES SURGICAL LASER SYSTEM  
For Reduction and Removal of Unwanted Hair**

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**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  
FXA: 408-934-1454

**DEVICE TRADE NAME**

Orion Series Surgical Laser System

**DEVICE COMMON NAME**

Laser Instrument, Surgical, Powered

**DEVICE DESCRIPTION:**

The Orion Series Surgical Laser System consists of a movable console containing power supplies, a treatment laser on a solid optical deck, and a cooling system to dissipate the heat generated by the system. A keypad control panel with CRT enables the user to control the laser system operating parameters.

Surgical power is controlled via a footswitch. Laser power is emitted only when the footswitch is depressed. The delivery system is through fiber optics.

Five configurations are currently available:

12W KTP only, 208 VAC  
12W KTP/30W Nd:YAG, 208 VAC  
20W KTP only, 208 VAC  
20W KTP/50W Nd:YAG, 208 VAC  
50W Nd:YAG only, 208 VAC

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#### **DEVICE CLASSIFICATION:**

The Orion 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 Orion 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 Orion Series Surgical Laser System (Q-Switched Nd:YAG configuration) is intended for the removal and reduction of unwanted hair.

#### **CLINICAL SUMMARY:**

This study incorporated a multi-center, randomized, unblinded design with an active, parallel control. The primary objective of the study was to establish the safety and effectiveness of the Laserscope Q-Switched Nd:YAG laser in the reduction of hair density in facial and non-facial anatomical areas. This clinical study was conducted in support of the 510(k) submission.

Convenience sampling was used to enter 70 patients at three geographically dispersed investigational centers. The average patient age was  $40.5 \pm 8.7$  years and the majority of the patients were female (79%). Describing the patient demographics entailed specifying each patient's Fitzgerald Classification, hair color, hair thickness, and hair weight. Fifty percent of the patients had a Fitzgerald Classification of II, 71% of the patients had black hair, 67% of the patients had course hair, and 54% of the patient's had hair described as heavy.

The number of sites treated was fairly uniform across all sites with some weighting toward Study Center #3 (45%). Among the 70 patients, 139 sites were treated. All, but one patient, had two treatments each. The treatment sites were stratified by location (facial vs. non-facial). Facial sites made up 34% of the treatments and non-facial sites accounted for 66% of the treatments.

All treatments were performed between June 8 and October 12, 1998. Laser energy settings ranged from  $100 \text{ J/cm}^2$  to  $153 \text{ J/cm}^2$ . The lower energy settings were confined to facial treatments, while the higher energy settings were required for the non-facial treatments. Total lasing time was restricted to 30 seconds for all patients.

One primary safety and three secondary efficacy study objectives were specified in the study protocol. In terms of safety, only one adverse event (i.e., extended erythema and burning

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sensation resolved within 10 minutes of treatment) was reported at the time of treatment (1.4%). No adverse events or complications were reported beyond the time of treatment.

With regard to effectiveness, the investigator was to visually estimate percent reduction in hair density at each follow-up interval. The mean estimate of hair reduction was 26% at 7 days, 49% at 30 days, and 36% at 90 days post-treatment. When this analysis was further stratified by study center, it was found that Study Center #3 heavily influenced the lower estimates at 90 days post-treatment. Multivariate analysis of variance for longitudinal data revealed a significant difference in mean hair reduction over time and a significant study center effect. However, the location of the treatment had no impact on the estimates.

The patient was also queried as to her or his visual estimate of percent reduction in hair density at each follow-up interval. The patients' mean estimate of hair reduction was 33% at 7 days, 45% at 30 days, and 33% at 90 days post-treatment. The values and trends seen with the patients' estimates did not deviate greatly from that seen with the investigators. When this analysis was further stratified by study center, it was found that Study Center #3 again heavily influenced the lower estimates at 90 days post-treatment. The repeated measures multivariate analysis of variance revealed a significant difference in mean hair reduction over time, a significant study center effect, and a significant treatment location effect. These findings suggest great variance in patient estimates from center to center over time. Also, there was consistently lower hair reduction estimates reported across time for the non-facial sites, but the difference in estimates across time was not dependent upon the location of the treatment.

The last efficacy outcome was the patient satisfaction with treatment. The patients were asked to rank their treatments on a scale from 1 to 5 with one being worse than baseline and 5 being an excellent result. At seven days post-treatment, there was a 57% probability that the patients would rate their treatments as "Fair" or better. At 30 days post-treatment, there was an 89% probability that the patients would rate their treatments as "Fair" or better. At 90 days post-treatment, there was a 70% probability that the patients would rate their treatments as "Fair" or better.

A treatment success was based on the investigator estimate of  $\geq 30\%$  hair reduction and a patient satisfaction ranking of "Fair" or better. The overall success rates were 38% at seven days after treatment, 86% at 30 days after treatment, and 58% at 90 days after treatment. Although there was a significant study center effect and hair weight effect, very little difference was seen in overall success rates for facial and non-facial treatments.

## TECHNOLOGICAL CHARACTERISTICS

The Orion Series Surgical Laser System generates optical power by solid state Nd:YAG laser resonators. The system operates at wavelength (1064 nm). The near-infrared wavelength of

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Summary of Safety and Effectiveness,  
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this laser system is within the range (600 - 1100 nm) The primary tissue chromophores competing for laser absorption are hemoglobin and melanin. The absorption coefficient between 755 nm and 1064 nm is similarly absorbed by melanin, and the longer wavelength allow greater dermal penetration. The operating mode of the laser system is Q-Switched.

The short pulse duration of this laser system enables it to be used for selective phototherolysis. The intended target tissue has a thermal relaxation time of approximately 1 microsecond and the pulse duration of the treatment laser light for this laser is in the nanosecond range. The pulses are, therefore preferentially absorbed by pigmented structures in the targeted tissue, causing selective heating and thermal damage of the pigmented structures. The Q-Switched Nd:YAG systems' faster repetition rates (1 - 20 Hz Orion) enables the user to conduct faster treatment sessions.

The laser system delivers spot sizes in the 2 - 4 mm range. A specification table for the Orion Series Surgical Laser System and predicate device is found in Table II.

**SUBSTANTIAL EQUIVALENCE DETERMINATION:**

Since the Orion Series Surgical Laser System is substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, 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.

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## SPECIFICATIONS

<b>SPECIFICATIONS</b>	<b>ORION SERIES SURGICAL LASER SYSTEM- Q SWITCHED CONFIGURATION</b>
<b>Laser Type</b>	<b>Nd:YAG/KTP</b>
<b>Wavelength</b>	<b>1064 nm/532 nm</b>
<b>Operating Parameter</b>	<b>Q-Switched</b>
<b>Energy Per Pulse</b>	<b>12.6 J/cm<sup>2</sup> at 2 ms pulse width (StarPulse) @ 1 mm spot size</b>
<b>Repetition Rate</b>	<b>1020 Hz (StarPulse), single shot</b>
<b>Q-Switched Pulse Width</b>	<b>Nd:YAG: 150 ± 50 ns KTP: 500 - 850 ns</b>
<b>Cooling</b>	<b>Closed cycle water to air heat exchanger</b>
<b>Electrical Supply</b>	<b>208V, single phase, 29A</b>
<b>Beam Delivery</b>	<b>Fiber Optic focusing handpiece; spot sizes 1, 2, 4 mm</b>
<b>Weight</b>	<b>380 pounds</b>
<b>Dimensions</b>	<b>28" long, 18" wide, 48" high</b>
<b>Clinical Applications</b>	<b>Removal of dark tattoo ink, including blue and black</b>

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K990718  
Trade Name: Orion Series Surgical Laser System and Accessories  
Lyra Surgical Laser System and Accessories  
Regulatory Class: II  
Product Code: GEX  
Dated: February 7, 2000  
Received: February 9, 2000

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.

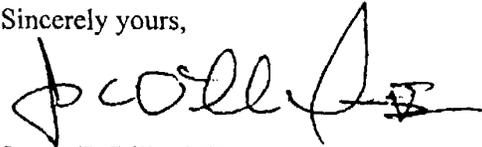
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is fluid and cursive, with a large initial "J" and a long horizontal stroke at the end.

James E. Dillard III  
Acting 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:

K990718

Device Name:

ORION SERIES SURGICAL LASER SYSTEM  
AND ACCESSORIES  
LYRA SURGICAL LASER SYSTEM AND  
ACCESSORIES

Indications for Use:

The Orion Series Surgical Laser System and the Lyra Surgical Laser System are intended for the lightening and removal of unwanted body hair in Fitzpatrick Skin Type I to VI using 1064 nm, Nd:YAG.

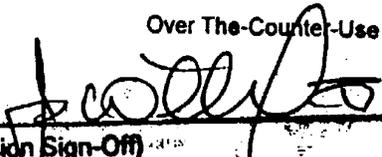
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  (per 21 CFR 801.109)

or

Over The-Counter-Use

  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K990718