K994273

JAN 20 2000

Summary of Safety and Effectiveness

Company Name: New Star Lasers, Inc.
11802 Kemper Road
Auburn, California 95603
(916) 823-1434

Company Contact: Donald V. Johnson
Director, Regulatory & Quality Affairs

Date Prepared: December 14, 1999

Device Name:

Trade Name: New Star Lasers Model 1000 Holmium Laser System

Common Name: Surgical Laser System

Classification Name: Instrument, Surgical, Powered Laser
21 CFR § 878.4810

Predicate Device: Omni Pulse™ Holmium Laser System, Model 1210
Trimedyne, Inc.
Irvine, California
K992574

Device Description:

The New Star Model 1000 is a compact, portable, self-contained system that produces a beam of infrared radiation at 2,100 nm wavelength for treatment, and a visible Helium Neon (HeNe) laser beam at 632.8 nm for aiming. The system emits a pulsed laser beam, which is delivered to the treatment site using a fiber-optic delivery system.

The system consists of a laser console, unit fiber-optic delivery system, and a footswitch The system provides safety features that are designed to protect the user and patient from high voltages and laser emissions.

Intended Use/Indications:

Incision, excision, resection, ablation, vaporization, coagulation, and hemostasis, with or without an endoscope, in Gastroenterological/Gastrointestinal Surgery, including:

Cholecystectomy, lysis of adhesions, appendectomy, biopsy, pylrosternotomy (sp?), benign and malignant lesions, rectal polyps of sigmoid colon, gall bladder calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias, and telangiectasias of the Osler-Weber-Rendu disease.

Incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications:

Dermatology and Plastic Surgery of soft, mucosal, fatty, and cartilaginous tissues, with or without an endoscope, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasia [facial, leg], and rosacea), corns, papillomas, and basal cell carcinomas.

General Surgery of soft tissues, including:

skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablation.

Genitourinary Surgery, including:

superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, and lesions of the external genitalia.

Gynecological Surgery during open and endoscopic procedures.

Lithotripsy and Percutaneous Urinary Lithotripsy, including:

fragmentation of urinary calculi, fragmentation of ureteral calculi, and fragmentation of kidney calculi.

Orthopedic Surgery in pathological soft and cartilaginous tissue in small and large joints, including:

knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinecular release, and debridement of the degenerative knees.

Otorhinolaryngology (ENT) Surgery in soft, mucosal, cartilaginous and bony tissue, including:

endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinectomy), and dacryocystorhinostomy (DCR).

Percutaneous Lumbar Discectomy, soft and cartilagineous tissue.

Comparison with Predicate Device:

See following table.

Technical Specifications Comparison

Specification	New Star Model 1000 10 Watt Holmium Laser System	Trimedyne 40 Watt OmniPulse Holmium Laser System
Laser source	Pulsed, solid-state Ho:YAG	Pulsed, solid-state Ho:YAG
Wavelength	2.1 microns	2.1 microns
Pulse width	350 microseconds nominal	350 microseconds nominal
Pulse repetition rate	5-12 Hz	5-25 Hz
Power output	10 watts	40 watts
Energy range per Pulse	0.5-1.25 Joules	0.5-3.5 Joules
Electrical service	115 VAC $\pm$ 10%, 10 amps, single phase, 50-60 Hz	220 VAC $\pm$ 10%, 30 amps, single phase, 50-60 Hz
Cooling	Self-contained air/water	Self-contained air/water
Aiming beam	1.5 mW red HeNe	5mW red HeNe
Dimensions	21"L x 14"W x 31"H	39"L x 26"W x 47"H
Weight	115 lbs.	600 lbs.
Indications	General/Orthopedic Surgery, PLDD, Sclerostomy, Endosinus (ENT), Soft Tissue (Urology), Lithotripsy (Ureteral)	General/Orthopedic/ Gastroenterological/ Gastrointestinal/ Dermatologic/ Genitourinary/ Gynecological/ Otorhinolaryngological (ENT) Surgery, PLDD, Lithotripsy (urinary, urethral, kidney, gall bladder, and biliary/bile duct calculi)
K Numbers	K912879, K920248, K921724, K933007, K942542, K945156	K992574

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

Mr. Donald V. Johnson
Director
Regulatory & Quality Affairs
New Star Lasers, Inc.
11802 Kemper Road
Auburn, California 95603

Re: K994273
Trade Name: Model 1000 Holmium Laser System
Regulatory Class: II
Product Code: GEX
Dated: December 14, 1999
Received: December 20, 1999

Dear Mr. Johnson:

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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K994273

Device Name: New Star Lasers, Inc. Model 1000 Holmium Laser System

Indications for Use:

The New Star Lasers, Inc. Model 100 Holmium Laser System is indicated for the following:

Incision, excision, resection, ablation, vaporization, coagulation, and hemostasis, with or without an endoscope, in Gastroenterological/Gastrointestinal Surgery, including:

Cholecystectomy, lysis og adhesions, appendectomy, biopsy, pylrosternotomy (sp?), benign and malignant lestions, rectal polyps of sigmoid colon, gall blader calculi, biliary/bile duct calculi, benign and malignant neoplasm, polyps, colitis, ulcers, angiodysplasia, hemorrhoids, varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, duodenal ulcer, non-bleeding ulcer, gastric erosions, colorectal cancer, gastritis, bleeding tumors, pancreatitis, vascular malformations, telangiectasias, and telangiectasias of the Osler-Weber-Rendu disease.

Incision, excision, resection, ablation, coabulation, hemostasis, and vaporization, with or without an endoscope, in the following indications:

Dermatology and Plastic Surgery of soft, mucosal, fatty, and cartilaginous tissues, with or without an endoscope, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasia [facial, leg], and rosacea), corns, papillomas, and basal cell carcinomas.

General Surgery of soft tissues, including:

skin incision, tissue dissection, excision or external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablation.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994273

Prescription Use X OR Over-the Counter Use _____
(Per 21 CFR 801.109)

Genitourinary Surgery, including:
superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, and lesions of the external genitalia.

Gynecological Surgery during open and endoscopic procedures.

Lithotripsy and Percutaneous Urinary Lithotripsy, including:
fragmentation of urinary calculi, fragmentation of urethral calculi, and fragmentation of kidney calculi.

Orthopedic Surgery in pathological soft and cartilaginous tissue in small and large joints, including:
knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinecular release, and debridement of the degenerative knees.

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