DEC 11 2009

Premarket Notification
510(k) Summary
(As Required by 21 CFR 807.93)

K092964

This 510(k) Summary of safety and effectiveness for the New Star Model CoolTouch Varia Nd:YAG Surgical Laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Submitter:	New Star Lasers, Inc. d.b.a. CoolTouch, Inc.
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Natalie Vollrath Quality and Regulatory Manager
Telephone/Fax/Email:	(916) 677-1912 – Phone (916) 677-1901 – Fax nvollrath@newstarlasers.com - Email
Date prepared:	September 24, 2009
Device Trade Name:	CoolTouch Varia Nd:YAG Surgical Laser
Common Name:	Nd: YAG Surgical Laser
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR §878.4810
Legally Marketed Predicate Devices:	• CoolTouch Varia Nd:YAG laser system • Patholase PinPointe FootLaser Nd:YAG laser system • Lumenis VersaPulse PowerSuite Ho:YAG/ Nd:YAG laser system
Device Description:	The CoolTouch Varia Laser System is an Nd:YAG laser producing laser emission at 1064 nm. The laser consists of a cabinet which houses the power supply, the cooling system, microcontroller, laser, foot switch, and the fiber optic for delivery of the laser energy with fiber optic handpiece setup.
Intended Use:	The soft tissue applications are for the coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissues including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Dermatology: For hair removal (destruction of hair follicles) in all skin types and for coagulation and hemostasis of

vascular lesions and soft tissue applications. In addition to the tissue types cited, 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. Also for the treatment of fine lines and wrinkles.

Endoscopic/Laparoscopic General Surgery: Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in endoscopic, laparoscopic surgery applications, including but not limited to cholecystectomy, appendectomy, vagotomy, and pyloromyotomy.

Gastroenterology: Tissue ablation and hemostasis in the GI tract; esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma; GI hemostasis; including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions, GI tissue ablation, including benign and malignant neoplasms, angiodysplasia; polyps, ulcer, colitis, and hemorrhoids.

General Surgery: Soft tissue in general surgery applications, skin incisions, 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 excision procedures such as 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 spetum.

Head and Neck/Otorhinolaryngology (ENT): Coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissue.

Hemostasis during surgery: Adjunctive coagulation and hemostasis (control of bleeding) during surgery (endoscopic, laparoscopic, and open procedures).

Neurosurgery: Hemostasis of pituitary tumor, meningioma, hemagioblastoma, AVMs, glioma, glioblastoma, astrocytoma, oligodendroglioma.

	Oculoplastics: Incision, excision, vaporization, ablation, and coagulation of soft tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation of the eyeball, exteneration of orbital contents. Orthopedics: Incision, excision, cutting, ablation and/or hemostasis of intra-articular tissue in orthopedic surgical and arthoscopic applications. Plastic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue. Pulmonary/Thoracic Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures. Thoracic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue, including lung tissue, in thoracic applications including but not limited to isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets. Urology: All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, and lesions of the external genitalia (including condyloma accuminata). Podiatry: Ablation, vaporization, incision, excision, and coagulation of soft tissue including matrixectomy, periungal and subungal warts, plantar warts, radical nail excision, and neromas.
Comparison:	The Cooltouch Varia has the same principle of operation, the same wavelength and essentially the same pulse energy rate as the predicate devices.
Nonclinical Perfomance Data	None
Clinical Performance Data:	None
Conclusion:	The CoolTouch Varia Nd:YAG Laser System is substantially equivalent to the predicate devices for the indications requested.
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

New Star Lasers, Inc
d.b.a. CoolTouch, Inc.
% Ms. Natalie R. Vollrath
QA/RA Manager
9085 Foothills Boulevard
Roseville, California 95747

DEC 11 2009

Re: K092964
Trade/Device Name: CoolTouch Varia Nd:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 24, 2009
Received: September 25, 2009

Dear Ms. Vollrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K092964

Device Name: CoolTouch Varia Nd:YAG Laser System

Indications for Use:

The soft tissue applications are for the coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissues including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Dermatology: For hair removal (destruction of hair follicles) in all skin types. For coagulation and hemostasis of vascular lesions and soft tissue applications. In addition to the tissue types cited, 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. Also for the treatment of fine lines and wrinkles.

Endoscopic/Laparoscopic General Surgery: Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in endoscopic, laparoscopic surgery applications, including but not limited to cholecystectomy, appendectomy, vagotomy, and pyloromyotomy.

Continued on next page

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Ogle for mcm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092964

Indications for Use—Continued

Gastroenterology: Tissue ablation and hemostasis in the GI tract; esophageal neoplastic obstructions including squamous cell carcinoma and adenocarcinoma; GI hemostasis; including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions, GI tissue ablation, including benign and malignant neoplasms, angiodysplasia; polyps, ulcer, colitis, and hemorrhoids.

General Surgery: Soft tissue in general surgery applications, skin incisions, 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 excision procedures such as 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 spetum.

Head and Neck/Otorhinolaryngology (ENT): Coagulation, photocoagulation, incision/excision, ablation, and vaporization of soft tissue.

Hemostasis during surgery: Adjunctive coagulation and hemostasis (control of bleeding) during surgery (endoscopic, laparoscopic, and open procedures).

Neurosurgery: Hemostasis of pituitary tumor, meningioma, hemagioblastoma, AVMs, glioma, glioblastoma, astrocytoma, oligodendroglioma.

Oculoplastics: Incision, excision, vaporization, ablation, and coagulation of soft tissues in oculoplastic procedures such as operations on the lacrimal system, operation on the eyelids, removal of biopsy or orbital tumors, enucleation of the eyeball, exteneration of orbital contents.

Orthopedics: Incision, excision, cutting, ablation and/or hemostasis of intra-articular tissue in orthopedic surgical and arthoscopic applications.

Plastic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue.

Pulmonary/Thoracic Surgery: Palliative treatment of benign and malignant pulmonary airway obstructions including squamous cell carcinoma, adenocarcinoma, carcinoid, benign tumors, granulomas, and benign strictures.

Thoracic Surgery: Incision, excision, cutting, coagulation, and vaporization of soft tissue, including lung tissue, in thoracic applications including but not limited to isolation of vessels for endarterectomy and/or by-pass grafts, wedge resections, thoractomy, formation of pacemaker pockets.

Continued on next page

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092964

Indications for Use—Continued

Urology: All applications including superficial urinary bladder tumors, invasive bladder carcinoma, urethral strictures, and lesions of the external genitalia (including condyloma accuminata).

Podiatry: Ablation, vaporization, incision, excision, and coagulation of soft tissue including matrixectomy, periungal and subungal warts, plantar warts, radical nail excision, and neromas.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092964