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NOV - 1 2011

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

This 510(k) Summary of safety and effectiveness for the New Star Model CoolTouch VariaBreeze 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 30, 2011
Device Trade Name:	CoolTouch VariaBreeze™ 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 (K092964) • PinPointe USA, Inc. PinPointe FootLaser Nd:YAG laser system (K093457)
Device Description:	The CoolTouch VariaBreeze Laser System is an Nd:YAG laser using a flashlamp-pumped solid state laser rod to produce laser emission at 1064 nm. The laser consists of a cabinet that houses the following: • Control panel with microcontroller and emergency stop button, standby button, ready button, and key switch • Connector port for fiber optic delivery system • Remote interlock connector • 630 to 680 nm diode aiming beam • Power supply • Cooling system • Connector port for footswitch and power cord

Delivery devices for the VariaBreeze include:

- CoolBreeze Handpiece for CoolBreeze Mode—Contains non-replaceable fiber optic within a flexible cable connected to the laser. A standoff at the tip allows for non-contact use, and a control dial is used to set the spot size from 2mm to 10mm. The handpiece also has cryogen for topical cooling. The handpiece is cleanable and reusable.

- Toenail Handpiece for Toenail Mode—The fiber optic cable attaches to the laser. The handpiece features a standoff at the tip to provide the correct placement for laser delivery to the treatment site and is reusable and cleanable.

Intended Use:

The CoolTouch VariaBreeze with CoolBreeze® Handpiece is intended for:

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

The CoolTouch VariaBreeze with Toenail Handpiece is intended for:

For use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

Comparison:

The Cooltouch VariaBreeze 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

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Technological Characteristics:

Characteristic	CoolTouch Varia Laser System K092964	CoolTouch VariaBreeze Laser System K103338
Laser Medium	Nd:YAG	Nd:YAG
Wavelength	1064 nm	1064 nm
Aiming Beam	532 nm	532 nm
Output Power (max)	36W max	30W
Energy per Pulse	Variable to 3.9 Joules	20-200 mJ, 500-1000 mJ
Pulse Duration	600 μsec	100-700 μsec
Exposure	Single pulse or repeat for continuous burst	Continuous
Repetition Rate	6-200 Hz	5-100 Hz
Spot Size	2 – 10 mm	2 – 10 mm
Dimensions	31"H x 18"W x 21"D	31"H x 18"W x 21"D
Weight	160 lbs (73kg) console	160 lbs (73 kg) console
Power Requirements	115VAC, 230VAC 50/60Hz	115VAC, 230VAC 50/60Hz

Characteristic	Patholase PinPointe FootLaser Laser Systems K093547			CoolTouch VariaBreeze Laser System K103338
Laser Medium	Nd:YAG			Nd:YAG
Wavelength	1064 nm			1064 nm
Aiming Beam	630-680 nm			532 nm
Output Power (max)	6W	30W	100W	30W
Energy per Pulse	20-200 mJ	20-1000 mJ	20-3500 mJ	20-200 mJ, 500-1000 mJ
Pulse Duration	100-700 μsec	350-3000 μsec	350-3000 μsec	100-700 μsec
Exposure	Continuous			Continuous
Repetition Rate	5-100 Hz			5-100 Hz
Spot Size	1 mm (published)			1 mm
Dimensions	14"H x 7"W x 16"D			31"H x 18"W x 21"D
Weight	36 lbs (16kg) console			160 lbs (73 kg) console
Power Requirements	90-130VAC, 200-240 VAC 50/60 Hz			115VAC, 230VAC 50/60Hz

Conclusion: The CoolTouch VariaBreeze Nd:YAG Laser System is substantially equivalent to the predicate devices for the indications requested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

New Star Lasers, Inc.
% Ms. Natalie Vollrath
Quality and Regulatory Manager
9085 Foothills Boulevard
Roseville, California 95747

Re: K103338
Trade/Device Name: CoolTouch VariaBreeze 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: PDZ, GEX
Dated: October 25, 2011
Received: October 25, 2011

Dear Mr. Vollrath:

This letter corrects our substantially equivalent letter of November 01, 2011.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

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

Enclosure

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Indications For Use Statement

510(k) Number:

Device Name: CoolTouch VariaBreeze Nd:YAG Laser System

Indications for Use:

For CoolTouch VariaBreeze™ with CoolBreeze® Handpiece:

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

For CoolTouch VariaBreeze™ with Toenail Handpiece:

Indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

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) Nil Ogle for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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