K101783

SEP 13 2010

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 CT3PZ/CoolTouch CT3 Plus CoolBreeze 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:	June 24, 2010
Device Trade Name:	CoolTouch CT3PZ/CoolTouch CT3 Plus CoolBreeze 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 CT3 Nd:YAG laser system • CoolTouch CT3S Nd:YAG laser system • CoolTouch Varia Nd:YAG laser system • Patholase PinPointe FootLaser Nd:YAG laser system
Device Description:	The CoolTouch CT3PZ Laser System is an Nd:YAG laser producing laser emission at 1320 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:	For use in dermatology for incision, excision, ablation, and vaporization with hemostasis of soft tissue; for treatment of fine lines and wrinkles; for mild to moderate inflammatory acne vulgaris; for back acne and atrophic scarring, and; for podiatry, (incision, excision, and coagulation of soft tissue) including matrixectomy, periungal and subungal warts, plantar warts, radical nail excision, and neuromas.

Comparison:	The Cooltouch CT3PZ has the same principle of operation, the same wavelength and essentially the same pulse energy rate as the predicate devices.
Nonclinical Perfomance Data	Bench testing data produced results that indicate the CT3PZ is effective for use in podiatry.
Clinical Performance Data:	None
Conclusion:	The CoolTouch CT3PZ 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 –WO66-G609
Silver Spring, MD 20993-0002

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

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Re: K101783
Trade/Device Name: CoolTouch CT3PZ/CoolTouch CT3 Plus CoolBreeze
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 02, 2010
Received: September 07, 2010

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. 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 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/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

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative 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 CT3PZ/CoolTouch CT3 Plus CoolBreeze

Indications for Use The CoolTouch Model CT3PZ Nd:YAG Surgical Laser is indicated for the following:

- for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue;
- for treatment of fine lines and wrinkles;
- for treatment of mild to moderate inflammatory acne vulgaris;
- for treatment of back acne and atrophic acne scars, and;
- for podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - matrixectomy
  - periungal and subungal warts
  - plantar warts
  - radical nail excision
  - neuromas

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 RP Dyle for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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