

KO 30453

Section 4  
510(K) Summary  
CoolTouch® Nd:YAG Laser System

MAY 12 2003

Applicant: New Star Lasers, Inc.

Address: 9085 Foothills Boulevard  
Roseville, CA 95747

Contact Person: Donald V. Johnson

Telephone / Fax / Email 916-677-1900 – Phone  
916-677-1901 – Fax

Preparation Date: February 5, 2003

Device Trade Name: CoolTouch® Nd:YAG Laser System  
CoolTouch® II Nd:YAG Laser System

Common Name: Nd:YAG Pulsed Surgical Laser

Classification Name: Instrument, Surgical, Powered, laser  
79-GEX, 21 CFR 878-4810

Legally Marketed Predicate Device: Candela Smoothbeam™ Laser System  
K014128 for treatment of back acne  
K022884 for treatment of atrophic acne scars

Description of the CoolTouch® Nd:YAG Laser Systems The CoolTouch® Nd:YAG Laser Systems are ND:YAG lasers producing laser emission at 1320nm. The lasers consist of three interconnected section: The cabinet which houses the power supply, cooling system , microcontroler and the laser, the fiber optics and the handpiece.

Intended use of the CoolTouch® Nd:YAG Laser Systems The CooTouch® Nd:YAG Laser System are indicated for the treatment of back acne and the treatment of atrophic acne scars.

Performance Data: None

Conclusion: The CoolTouch® Nd:YAG Laser System is substantially equivalent to other existing laser systems in commercial distribution for treatment of back acne and treatment of atrophic acne scars.



MAY 12 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Donald V. Johnson  
Vice President, Operations  
New Star Lasers, Inc.  
9085 Foothills Boulevard  
Roseville, California 95747

Re: K030453

Trade/Device Name: CoolTouch Nd:YAG Laser System  
CoolTouch II 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: II  
Product Code: GEX  
Dated: February 11, 2003  
Received: February 11, 2003

Dear Mr. Johnson:

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 such 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); 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.

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This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*for* 

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: Pending K030453

Device Name: CoolTouch® ND:YAG Laser System

Indications for Use:

**The CoolTouch® ND:YAG Laser System is indicated for:**

- 1. treatment of back acne**
- 2. treatment of atrophic acne scars**

(Please do not write below this line - Continue on another page if needed)

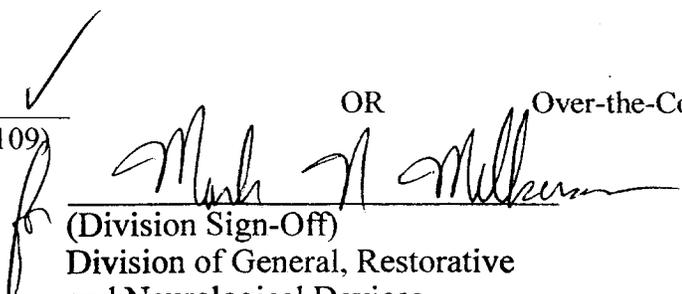
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(per 21 CFR 801.109)

OR

Over-the-Counter Use

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K030453