

Summary of Safety and Effectiveness

K060966

This 510(k) Summary of Safety and Effectiveness for the CoolTouch "Varia" laser system is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92 and 21 CFR § 807.93 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) Summary.

Applicant: CoolTouch, Inc.

Address: 9085 Foothills Blvd.
Roseville, CA 95747 -

JUL 31 2006

Company Contact: Donald V. Johnson
Vice-President of Operations

Telephone: (916) 677-1912
(916) 677-1901 (FAX)

Date Summary Prepared: March 31, 2006

Device Name: CoolTouch, Inc. Model "Varia"
Nd:YAG Surgical Laser System

Common Name: Laser Instrument, Surgical Laser System and Accessories

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

Predicate Device: "Lyra" Long Pulse Nd:YAG Laser, Laserscope, San Jose, CA

Device Description: The CoolTouch, Inc. CoolTouch "Varia" Nd:YAG Surgical Laser is a laser producing emissions at 1064nm. The lasers consist of several interconnected sections: the *cabinet*, which houses the power supply, cooling system, microcontroller, and the laser head, the *fiber optics*, and the *handpiece*. The systems provide safety features that are designed to protect the user and patient from high voltages and laser emissions.

Intended Use/Indications:

The CoolTouch Varia Laser System and accessories are indicated for use in Dermatological applications for the treatment of fine lines and wrinkles.

**Performance
Standards:**

The CoolTouch "Varia" laser system complies with the appropriate sections of 21 CFR §1010 and 21 CFR § 1040.

**Substantial Equivalence
Statement:**

Based on the information in the premarket notification, the CoolTouch, Inc. believes that the "Varia" Nd:YAG laser system is substantially equivalent to the cited legally marketed predicate device for the indications requested.

April 6, 2006



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

CoolTouch, Inc.
% Mr. Donald V. Johnson
Vice President of Operations
9085 Foothills Boulevard
Roseville, California 95747

Re: K060966

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: II

Product Code: GEX

Dated: June 29, 2006

Received: June 30, 2006

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

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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.

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 (240) 276-0115. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K060966

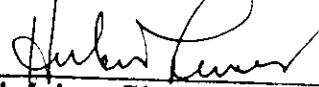
Device Name: CoolTouch Varia Nd:YAG Laser System

Indications for Use Statement:

The CoolTouch Varia Laser System and accessories are indicated for use in Dermatological applications for the treatment of fine lines and wrinkles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Prescription Use
(Per 21 CFR 801.109)

OR Over-the-Counter Use
510(k) Number K060966