SEP 2 8 2004

CoolTouch Inc.
CoolTouch NS-160 Nd:YAG Laser System
510(k) Premarket Notification
510(k) SUMMARY K04 0921

This 510(k) summary of safety and effectiveness for the CoolTouch NS-160 Nd:YAG Laser System is submitted in accordance with the requirements of SMDA of 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	CoolTouch Inc.
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Donald V. Johnson Vice-President of Operations
Telephone:	(916) 677-1912
Facsimile:	(916) 677-1901
Date Prepared:	April 6. 2004
Device Trade Name:	CoolTouch Model NS-160 Nd:YAG Laser System
Common Name:	Nd: YAG Surgical Laser
Classification Name:	Laser Surgical Instrument. 21 C.F.R. § 878.4810
Legally Marketed Predicate Device:	Diomed 810nm Surgical Laser, K023543, K012398 Biolitec Ceralas D10-60 810nm Diode Laser, K030700 Biolitec Ceralas D 980nm Diode Laser, K024088
Description of the CoolTouch Nd:YAG Laser Systems:	The CoolTouch NS-160 Nd:YAG Laser System is an ND:YAG laser producing laser emission at 1320 nm. The laser consists of two sections: The cabinet, which houses the power supply, cooling system, microcontroller and the laser, and the fiber optic.
Intended use of CoolTouch Nd:YAG Laser Systems:	The CoolTouch NS-160 Nd:YAG Laser System is indicated for the treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities.
Nonclinical Performance Data:	None

Clinical Performance Data:	Clinical data produced results that indicate that the CoolTouch Nd:YAG Laser System is effective in the treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities.
Conclusion:	The CoolTouch NS-160 Laser System is indicated for the treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities. The CoolTouch NS-160 is substantially equivalent to the predicate devices with the same intended use.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2004

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

Re: K040921
Trade/Device Name: CoolTouch NS-160 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: August 16, 2004
Received: August 19, 2004

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.

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. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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: K040921

Device Name: CoolTouch NS-160 Nd:YAG Laser System

Indications for Use:

The CoolTouch NS-160 Nd:YAG Laser System is indicated for the treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

Prescription Use X **510(k) Number** OR K040921 ~~Over the~~-Counter Use ____
(per 21 CFR 801.109)