NOV 17 2004

510(k) SUMMARY

K041323

CoolTouch, Inc.

PRIMA Pulsed Light Therapy System
510(k) Premarket Notification

Submitter:	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:	May 13, 2004
Device Trade Name:	PRIMA Pulsed Light Therapy System
Common Name:	Pulsed Light for Thermolysis/Photoepilation
Classification Name:	Instrument, Surgical, Powered, Laser. 79-GEX, 21 C.F.R. § 878.4810
Legally Marketed Predicate Devices:	New Star Lasers, Inc. UV-300 Pulsed Light Therapy System, Radiancy, Inc. SkinStation™ Pulsed Light System, Palomar Estelux™ Pulsed Light Therapy System.
Description of the New Star PRIMA Pulsed Light Therapy System:	The CoolTouch PRIMA Pulsed Light Therapy System is a compact, self-contained system that delivers a beam of pulsed light at wavelengths of 300nm to 1400nm, which can be optimized at various wavelength ranges and delivered to the treatment site. The system consists of a control console unit, which houses the power supply, cooling system, cryogen source, and microcontroller, the handpiece, which contains the light source, and the footswitch.
Intended use of the New Star PRIMA Pulsed Light Therapy System:	The CoolTouch PRIMA Pulsed Light Therapy System is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, vascular lesions, rosacea, hemangiomas, leg veins, hair removal, tattoos, pigmented lesions, pigmented lesions, lentigenes, and mild to

	moderate inflammatory acne vulgaris.
Nonclinical Performance Data:	None.
Clinical Performance Data:	None.
Additional Information:	None requested at this time
Conclusion:	The CoolTouch PRIMA Pulsed Light Therapy System is substantially equivalent to other existing pulsed light systems in commercial distribution for treatment of psoriasis, vitiligo, atopic dermatitis (eczema) seborrheic dermatitis, vascular lesions, rosacea, hemangiomas, leg veins, hair removal, tattoos, pigmented lesions, pigmented lesions, lentigenes, and mild to moderate inflammatory acne vulgaris.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

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

Re: K041323
Trade/Device Name: CoolTouch PRIMA Pulsed Light Therapy 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: November 4, 2004
Received: November 5, 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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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: K041323

Device Name: CoolTouch PRIMA Pulsed Light Therapy System

Indications for Use:

The CoolTouch PRIMA Pulsed Light Therapy System is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, vascular lesions, rosacea, hemangiomas, leg veins, hair removal, tattoos, pigmented lesions, lentigenes, and mild to moderate inflammatory acne vulgaris.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use____
(per 21 CFR 801.109)

Miriam C. Provost

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

510(k) Number K041323