FEB 2 4 2005

510(k) Summary

Applicant & Submitter:	Care Electronics, Inc.
Address:	4700 Sterling Dr., Suite D Boulder, CO 80301
Phone:	303-444-2273
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Contact Person:	Thomas Moody
Preparation Date:	12/23/04
Device Submitted:	Dermillume Phototherapeutic Lamp
Proprietary Name:	Dermillume
Common Name:	Blue/Red Light Acne Treatment Lamp
Classification:	Class II Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product code: GEX
Predicate Devices:	ClearLight, Phototherapy System, Model Cl 420 (K013623), BLU-U, Model 4710 (K031805), Omnilux Blue (K030883), & Omnilux Red (K030426)
Device Description:	The Dermillume Pro1000 device is a compact light source that delivers high intensity narrow band blue and red light to the body for the treatment of acne vulgaris. The light sources are narrow wavelength LEDs that supply a spectral output of 414 ± 5 nm (blue) and 633 ± 5 nm (red). The device supplies 20 and 10 mW/cm^2 for blue and red light, respectively, at 4.6 inches distance from the skin surface. The principal parts of the device are a light unit, positioning arm and firmware timer to control duration of exposure. Additional off-the-shelf electronic devices related to treatment data acquisition and storage may be supplied as user options.
Intended Use:	The Dermillume Pro1000 phototherapy lamp is intended for dermatological use by trained licensed practitioners, specifically for the treatment of mild to moderate inflammatory acne vulgaris.

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Performance Data:

The performance data obtained from bench testing of the Dermillume device substantiates that the irradiance at a practicable distance from the skin surface (4.6") is comparable with the cited predicated devices. Additionally, the submission data demonstrates that the irradiance at the target surface is in conformance with recommendations of current clinical studies.

The mode of operation, treatment area, and general principles for the treatment of inflammatory acne vulgaris with this device are the same as the predicate devices, ClearLight, Phototherapy System, Model CI 420 (K013623), BLU-U, Model 4710 (K031805), Omnilux Blue (K030883) for the reduction and elimination of the acne-producing bacterium *P. acnes*.

The Dermillume device combines the inflammatory acne-reducing properties of blue light with the red light improvement supported by a recent clinical acne treatment study. The output wavelength and irradiance are comparable to the predicate device, Omnilux Red (K030426).

There are no significant adverse reactions observed in clinical studies using this technology. The device is safe and efficacious.

Substantial Equivalence:

The Dermillume Pro1000 phototherapeutic lamp is substantially equivalent to the cited predicate devices for spectral output, mode of operation, operating principals as well as general and specific indications for use. All devices emit visible light for the treatment of dermatological conditions. Although there are some differences in the source of the emitted light and output intensity, these differences are minor and do not raise new questions of safety or efficacy.

The Dermillume Pro1000 phototherapeutic lamp is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Thomas O. Moody
President
Care Electronics, Inc.
4700 Sterling Drive, Suite D
Boulder, Colorado 80301

Re: K043575
Trade/Device Name: Dermillume Pro1000
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: January 20, 2005
Received: January 25, 2005

Dear Mr. Moody:

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/industry/support/index.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

Indications for Use

510(k) Number (if known): K043575

Device Name: Dermillume Pro1000

Indications For Use: The Dermillume Pro1000 phototherapy lamp is intended for dermatological use by trained licensed practitioners, specifically for the treatment of mild to moderate inflammatory acne vulgaris.

Prescription Use __Yes__ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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

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