K051259

SEP 20 2005

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's name:	TheraLight, Inc.
Submitter's Address:	2794 Loker Avenue West, Suite 105 Carlsbad, CA 92008
Telephone:	(760) 930-8000
Contact:	Kevin E. Daly Chief Operating Officer
Date Prepared:	May 13, 2005
Device Trade Name:	VersaClear™ Skin Therapy System
Device Common Name:	VersaClear™ Skin Therapy System
Device Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (ref. 21 CFR 878.4810); Ultraviolet lamp for dermatologic / skin disorders (ref. 21 CFR 878.4630).
Predicate Devices:	Blu-U Photodynamic Therapy Illuminator Dusa Pharmaceuticals, Inc. K031805 Omnilux Blue Photo Therapeutics, Ltd. K030883 Omnilux Red Photo Therapeutics, Ltd. K030426 Omnilux Revive and Blue Photo Therapeutics, Ltd. K043329 HOUVA II UVA National Biological Corporation K885025 HOUVA 3 Phototherapy System National Biological Corporation K041212

Predicate Devices (cont'd): UV 1000
Waldmann Lichttechnik
K841795

Device Description:

The VersaClear™ Skin Therapy System is a 120/240V 50/60 Hz AC illumination source consisting of one or more light modules. A set of light modules emits a specific narrow spectrum of light, namely blue (420 ± 2nm), red (615 ± 3nm), or UVA (368 ± 3nm). The light modules are mounted on a positioning arm attached to a mobile or stationary pedestal, a wall, or a countertop. This flexible design accommodates varying office spatial settings, and allows for the treatment of patients who are sitting, reclining, or lying down. Light modules are interchangeable to maximize System versatility.

Intended Use and Indications for Use:

The VersaClear System is intended to provide phototherapeutic light to the body. The VersaClear is generally indicated to treat dermatological conditions. Blue light modules are indicated to treat moderate inflammatory acne vulgaris. Red light modules are indicated for use in combination with blue light for the treatment of moderate inflammatory acne vulgaris, and for use alone in the treatment of superficial, benign vascular, and pigmented lesions. UVA light modules are indicated for individuals who require specific ultraviolet radiation therapy for diagnosed skin disorders.

Performance Data:

The performance characteristics of the VersaClear System are substantially similar to the cited predicate devices. The technological differences do not raise new types of safety or efficacy issues. On this basis, the VersaClear System is substantially equivalent to the predicate devices.

Conclusion:

On the basis of the information provided in this Summary, TheraLight believes that the VersaClear Skin Therapy System is substantially equivalent to legally commercialized predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2005

Mr. Kevin E. Daly
Chief Operating Officer
TheraLight, Inc.
2794 Loker Avenue West, Suite 105
Carlsbad, California 92008-6616

Re: K051259
Trade/Device Name: VersaClear™ Skin 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, FTC
Dated: September 2, 2005
Received: September 6, 2005

Dear Mr. Daly:

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,

Mark N. Melkerson
Acting 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): K051259

Device Name: VersaClear™ Skin Therapy System

Indications for Use:

The VersaClear Skin Therapy System is generally indicated to treat dermatological conditions. Blue light modules are indicated to treat moderate inflammatory acne vulgaris. Red light modules are indicated for use in combination with blue light modules for the treatment of moderate inflammatory acne vulgaris, and for use alone the treatment of superficial, benign vascular, and pigmented lesions. UVA light modules are indicated for individuals who require specific ultraviolet radiation therapy for diagnosed skin disorders.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

Barbara Bucknp for MKM

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

510(k) Number K051259