MAY 25 2006

K061295

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, 2006
Device Trade Name:	VersaClear™ Skin Therapy System UVA (350nm) Light Module
Device Common Name:	VersaClear™ Skin Therapy System UVA (350nm) Light Module
Device Classification Name:	Ultraviolet lamp for dermatologic / skin disorders (ref. 21 CFR 878.4630).
Predicate Devices:	Flex Controlled Phototherapy Equipment Daavlin Distributing Company K050695

Device Description:

The VersaClear™ Skin Therapy System UVA (350nm) Light Module is a 120/240V 50/60 Hz AC illumination source that emits UVA radiation with a peak at 350nm ± 5 mm.

Intended Use and Indications for Use:

The VersaClear™ Skin Therapy System UVA (350nm) Light Module is indicated for individuals who require specific ultraviolet radiation therapy for diagnosed skin disorders.

Performance Data:

The VersaClear™ Skin Therapy System UVA (350nm) Light Module emits UVA radiation at a peak of 350nm ±5nm and a bandwidth (Full Width at Half Maximum) of 40nm, and a nominal skin irradiance of from 10-35 mW/cm^2.

Conclusion:

The VersaClear Skin Therapy System is substantially equivalent to legally commercialized UV phototherapy devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

TheraLight, Inc.
% Mr. Kevin E. Daly
Chief Operating Officer
2794 Loker Avenue West, Suite 105
Carlsbad, California 92010

Re: K061295
Trade/Device Name: VersaClear™ Skin Therapy UVA (350nm) Light Module
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: May 8, 2006
Received: May 9, 2006

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
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): K061295

Device Name: VersaClear™ Skin Therapy System UVA (350nm) Light Module

Indications for Use:

The VersaClear Skin Therapy System UVA (350nm) Light Module is indicated for individuals who require specific ultraviolet radiation therapy for diagnosed skin disorders.

Prescription Use X OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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

510(k) Number K061295