K024020 1/5

JAN 17 2003

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 92008-6616
Telephone:	(760) 930-8000
Contact:	Kevin E. Daly
Date Prepared:	December 2, 2002
Device Trade Name:	UV120-2 UVA / UVB Phototherapy System
Device Common Name:	Targeted UVA / UVB Phototherapy System
Device Classification Name:	Ultraviolet lamp for dermatologic / skin disorders (ref. 21 CFR 878.4630)
Predicate Devices:	TheraLight, Inc. UV120-2 UVA / UVB Phototherapy System K022165 Lumenis, Ltd. BClear UVB Phototherapy System K020591 PhotoMedex, Inc. XTRAC Excimer Laser Phototherapy System K020847

K024020 2/2

Device Description:

The TheraLight UV120-2 UVA / UVB Phototherapy System is a microprocessor-controlled, high-intensity ultraviolet light source. The desired dose of UVA or UVB light is selected using controls on the System front panel. The System provides "targeted" phototherapy, whereby the specified dose of UVA or UVB light is delivered via a flexible Lightguide and Handpiece. The System delivers a homogenous UV light dose to a localized ¾" square patch of skin without exposure to neighboring, healthy tissues.

Intended Use:

The TheraLight UV120-2 UVA / UVB Phototherapy System is intended for use in PUVA photochemistry and UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the System UVB channel is indicated for the treatment of leukoderma.

Performance Data:

The TheraLight UV120-2 UVA / UVB Phototherapy System currently is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema) and seborrheic dermatitis. System performance data (UVB output spectra) is the same or very similar that for the claimed predicate devices.

Conclusion:

On the basis of the information provided in this Summary, TheraLight, Inc. believes the UV120-2 UVA / UVB Phototherapy 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

JAN 17 2003

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

Re: K024020
Trade/Device Name: UV120-2 UVA/UVB Phototherapy System
Regulation Number: 878.4630
Regulation Name: Ultraviolet lamp for dermatologic/skin disorders
Regulatory Class: Class II
Product Code: FTC
Dated: December 3, 2002
Received: December 5, 2002

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K024020

Device Name: TheraLight UV120-2 UVA/UVB Phototherapy System

Indications for Use:

The TheraLight UV120-2 UVA / UVB Phototherapy System is indicated for use in PUVA photochemistry and UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the System UVB channel is indicated for the treatment of leukoderma.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C. Provost

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

510(k) Number K024020