FEB 1 3 2004

510(k) Summary

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

Date:	December 12, 2003
Submitter's name:	Lerner Medical Devices, Inc.
Submitter's Address:	1545 Sawtelle Ave. Suite 36 Los Angeles, CA 90025
Submitter's Telephone:	(310) 914 0091
Submitter's Fax:	(310) 914 0095
Contact Person:	Zafirios F. Gourgouliatos, Ph.D., President
Device Trade Name:	Levia Phototherapy System
Device Common Name:	Targeted UVB Phototherapy System
Device Classification Name:	Ultraviolet lamp for dermatologic / skin disorders
Regulation Number:	878.4630
Product Code:	FTC
Classification:	Device Class II
Establishment Reg. Number:	Not obtained yet
List of Predicate Devices:	TheraLight, Inc. UV1 20-2 UVA / UVB Phototherapy System K022165, K024020, Lumenis, Ltd. BClear UVB Phototherapy System K020591, K021762 National Biological, Corp. Handisol Wound Healing K982082 National Biological, Corp. Panosol II UVB-206 K904427

Device Description:

The Levia Phototherapy System is an ultraviolet Light Source and energy delivery system. The System emits UV-B (290-320 nm) light for use in phototherapy and allows delivery of controlled doses. The desired dose is selected using controls on the panel of the Light Source and activated with a switch on the panel or remotely by a foot switch. A Spot Handpiece and a Fiber-optic Brush allow for selective treatment of skin lesions without exposure to neighboring, healthy tissues. The Spot Handpiece and Fiber-optic Brush connect to Light Source with a flexible Light Guide. The system is powered by a common household AC outlet. Protective eyewear is supplied with the system.

Indications for Use:

The Levia Phototherapy System is intended for use in UVB phototherapy for the treatment of psoriasis including scalp psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma.

The Levia Phototherapy System is intended for use on all skin types (I -VI).

Substantial Equivalence:

The Levia Phototherapy System emits UVB light within the spectral band of 290 -320 nm similar to that of the predicate device Panosol II UVB-206 device (K904427). This light has been shown to be safe and effective in the treatment of scalp psoriasis.

The major difference between the Levia Phototherapy System and the cited predicate devices is the Fiber-optic Brush used to treat affected areas of the skin that is covered by hair. Lerner Medical Devices, Inc. believes that this difference is an added convenience and does not raise new questions about safety or effectiveness.

Performance Data:

Performance data were submitted as part of the 510(k) application to confirm that the spectral output of the Levia System is between 290 and 320 nm, which is similar to spectra emitted by predicate devices. Other performance data included in the application show that the technological specifications are similar to those of the claimed predicate devices.

Conclusion:

On the basis of the information provided in this summary, Lerner Medical Devices, Inc. believes the Levia 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

FEB 1 3 2004

Lerner Medical Devices, Inc.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K040062
Trade/Device Name: Levia Phototherapy System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: January 22, 2004
Received: January 29, 2004

Dear Mr. Devine:

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). 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

Indications for Use

510(k) Number (if known): **K040062**

Device Name: Levia Phototherapy System

The Levia Phototherapy System is intended for use in UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma.

The Levia Phototherapy System is intended for use on all skin types (I -VI).

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(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

510(k) Number K040062