K091568

510(k) Summary

NOV - 5 2009

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

Date:	May 27, 2009
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., Chief Science Officer Management Representative
Device Trade Name:	LH-75 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:	3006793564
List of Predicate Devices:	TheraLight, Inc. UV1 20-2 UVA / UVB Phototherapy System K022165, K024020, Lerner Medical Devices, Inc. LH-75T Phototherapy System K090097 Daavlin Distributing Co. 3 Series Phototherapy Cabinet K063621 Daavlin Distributing Co. Flex Controlled Phototherapy Equipment K050695

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Lerner Medical Devices, Inc.
% Zafirios Gourgouliatos, Ph.D.
Chief Science Officer and
Management Representative
1545 Sawtelle Boulevard, Suite 36
Los Angeles, California 90025

Re: K091568
Trade/Device Name: LH-75 Phototherapy System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: October 23, 2009
Received: November 02, 2009

Dear Dr. Gourgouliatos:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number _____

Device Name: LH-75 Phototherapy System

The LH-75 Phototherapy System is intended for use, by or under the direction of a physician, in UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma.

The LH-75 Phototherapy System is intended for use on all skin types (I -VI).

Prescription Use ___X___ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark B Olsen for AXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091568