K103540 pg 1 of 3

FEB 10 2011

ENCLOSURE E

Non-Confidential 510(k) Summary of Safety and Effectiveness

Psoria-Shield Inc.
6408 W. Linebaugh Avenue
Suite 104
Tampa, FL 33625

Official Contact:	Scot Johnson Chief Technology Officer
Trade/Device Name:	Psoria-Light Model PS1000
Device Common Name:	Targeted UVA / UVB Phototherapy System
Regulation Number:	878.4630
Regulation Name:	Ultraviolet lamp for dermatologic disorders
Regulatory Class:	Class II
Product Code:	FTC
Predicate Devices:	This product is substantially equivalent in design, composition, and function to: TheraLight Inc. DuaLight UV120-2 UVA/UVB Phototherapy System K024020 PhotoMedex, Inc. XTRAC Ultra^2 Excimer Laser System, Model AL10000 K073659

K103540 Pg 2 of 3

ENCLOSURE E

Non-Confidential 510(k) Summary of Safety and Effectiveness

Device Description:

Psoria-Light™ Model PS1000 delivers targeted ultraviolet (UV) light to small regions of affected skin (2.88 cm^2), sparring healthy skin. The system is capable of delivering either UVB light (300 to 320nm) or UVA light (350 to 395nm). Psoria-Light™ Model PS1000 generates both UVA and UVB light via LED technology, avoiding environmental concerns associated with disposal and exchange of mercury gas lamps, Xenon, and Chlorine gases commonly associated with targeted UV phototherapy devices. Psoria-Light's™ UVB LEDs emit light between 300 and 320 nm, avoiding light emissions below 300nm.

Psoria-Light™ Model PS1000 incorporates a unique safety feature, a non-contact sensor located about the aperture of the handpiece that detects human skin. The trigger mechanism for UV dosage administration (located on the handpiece) is disabled until a suitable surface is detected by this sensor.

Labeling and Instructions for Use:

See Proposed Labeling and Instructions for Use in sections J and Q respectively.

Intended Use:

The Psoria-Light Model PS1000 is indicated for use in targeted PUVA photochemistry and UVB phototherapy for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the system UVB channel is indicated for the treatment of leukoderma.

Substantial Equivalence:

The characteristics of the Psoria-Shield Psoria-Light Model PS1000 are substantially equivalent to those of the predicate devices. Operation of the predicate devices, including output wavelengths, power, and light sources have received 510(k) clearance previously for these type of treatments.

Clinical Performance Testing:

All clinical indications requested in this application have been previously cleared in the identified predicate devices. The Psoria-Light Model PS1000 does not introduce any new indications for use, and will perform in a substantially equivalent manner as the identified predicates. Therefore Psoria-Shield believes duplicative clinical data is not required as a condition of granting market clearance for the Psoria-Light Model PS1000.

ENCLOSURE E

Non-Confidential 510(k) Summary of Safety and Effectiveness

Product Performance Testing:

Testing and certification relevant to the Psoria-Light Model PS1000 includes conformance to current applicable international IEC 60601 series of standards, 21 CFR Part 1040.10, Performance Standard for Light-Emitting Products and certification to the UL 60601-1 Medical Electrical Equipment classification standard. Product will also comply with EMC (Electromagnetic Compatibility) requirements per FCC rules part 15, IEC 60601-1-2 and its particular Standards for susceptibility and emissions, as well as EN55011. The Psoria-Light Model PS1000 has been reviewed for risk management utilizing ISO 14971, Application of risk management to medical devices ensuring all aspects of the device are reviewed for potential hazards.

The Psoria-Light Model PS1000 shall have completed all testing to the standards and procedures identified in this submission prior to any product being released for sale. Products shall be produced and distributed by a facility that has been registered with the FDA to manufacture medical devices.

Conclusions:

The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is Substantially Equivalent to the predicate devices and it does not introduce any new issues of safety or efficacy. The Indications for Use and methods of operation are substantially equivalent to the predicates for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and of leukoderma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Psoria-Shield, Inc.
% Technireg, Inc.
Mr. Wayne Glover
19404 Pine Valley Drive
Odessa, Florida 33556

FEB 10 2011

Re: K103540
Trade/Device Name: Psoria-Light Model PS 1000
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: November 30, 2010
Received: December 02, 2010

Dear Mr. Glover:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

ENCLOSURE D

INDICATIONS FOR USE

510(k) Number (if known): K103540 PJ 1 of 2

Device Name: Psoria-Light Model PS1000

Indications for Use: The Psoria-Light Model PS1000 is indicated for use in targeted PUVA photochemistry and UVB phototherapy for the treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. In addition, the system UVB channel is indicated for the treatment of leukoderma.

Prescription Use _X_ **and/or** **Over-the-counter use** ___
(Per 21 CFR 801 Subpart D) (Per 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)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103540