K073587

510(k) Summary

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

Submitter's Name:	The Daavlin Distributing Company
Registration Number:	1526255

JAN 18 2008

Address:	205 West Bement Street Bryan, Ohio 43506
Telephone:	419.636.6304
Contact:	David W. Swanson
Date Prepared:	September 21, 2007
Device Trade Name:	DermaPal®
Device Common Name:	Hand Held Ultraviolet Phototherapy Unit
Device Classification:	Class II
Product Code:	FTC
Regulation Number:	CFR 878.4630
Regulation Name:	Ultraviolet lamp for dermatologic/skin disorders
Predicate Device:	Daavlin Distributing Company DermaPal® K022104

Device Description:

The DermaPal® a hand held ultraviolet light-emitting medical device.

The DermaPal® integrated operator interface consists of three main components: a LCD, a Membrane with 4 buttons, and a lamp wand. When the operator sets the treatment time and begins the treatment the lamp illuminates, emitting ultraviolet light through the wand. The operator holds the wand over the effected area(s) of the body. When the time set on the DermaPal® timer has elapsed, the lamps turn off. The DermaPal® is also equipped with an integrated comb, which is removable. The comb allows for easier treatment of effected areas of skin covered by hair, such as the scalp.

Predicate Device Comparison:

The DermaPal® with Digital Timer is constructed in the same design configuration as the predicate device, utilizing identical energy sources (UV lamps) and materials of identical composition. The DermaPal® with Digital Timer varies from the predicate device, in that the control system hardware and software has been updated to utilize current technology. The intended use, general and specific indications for use, spectral output, mode of operation, labeling, treatment area, and general operating principals of the DermaPal® hand held ultraviolet light-emitting medical device are the same or similar to those of the predicate device.

Intended Use:

The DermaPal® with Digital Timer is a hand held ultraviolet light emitting fluorescent lamp. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

Performance Data:

The DermaPal's® with Digital Timer's performance data is the same as or very similar to that of the claimed predicate device. The ultraviolet light tubes and construction used in the production of the predicate device and the DermaPal® with Digital Timer device are the same.

Conclusion:

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the DermaPal® with Digital Timer is substantially equivalent to the legally commercialized predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Daavlin Distributing Company
% Ms. Tara Mansur
Management Representative
205 West Bement Street
Bryan, Ohio 43506

Re: K073587
Trade/Device Name: DermaPal®
Regulatory Number: 21 CFR 878.4630
Regulatory Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: December 10, 2007
Received: January 2, 2008

Dear Ms. Mansur:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indication for Use

510(k) Number

Device Name DermaPal®

Indications for Use

The DermaPal® is a hand held ultraviolet light emitting fluorescent lamp. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) 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)

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

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