K063621

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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
	JAN 17 2007
Registration Number:	1526255
Address:	205 West Bement Street Bryan, Ohio 43506
Telephone:	419.636.6304
Contact:	David W. Swanson
Date Prepared:	October 30, 2005
Device Trade Name:	3 Series PC & SP Phototherapy Cabinet
Device Common Name:	Ultraviolet Phototherapy Cabinet
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 Spectra 300 Series Ultraviolet Phototherapy Cabinet K828654

K063621

Daavlin Distributing Company
3 Series S Phototherapy Cabinet
Ultraviolet Phototherapy Cabinet
K042502

Device Description:

The 3 Series PC & SP phototherapy cabinet is a microprocessor controlled full body fluorescent ultraviolet light source, with spectral output at peak wavelengths of 311 nm (Narrow Band UVB) and 350 nm (UVA). It is intended for use by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema). The desired dose is selected using the operator interface located on the front panel of the device. The 3 Series delivers full body phototherapy, whereby fluorescent tubes, which surround the patient, deliver the specified dose of UVA and/or UVB light.

Predicate Device Comparison:

The 3 Series PC & SP phototherapy cabinet is constructed in the same design configuration as the predicate device, utilizing identical energy sources (UV lamps) and materials of identical composition. The 3 Series varies from the predicate device, in that the control system hardware and software of the 3 Series 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 3 Series PC & SP are the same or similar to those of the predicate device.

Intended Use:

The Daavlin 3 Series PC & SP full body phototherapy cabinet is a medical ultraviolet light source, which is intended for use by or under the direction of a licensed physician for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

Performance Data:

The Daavlin 3 Series PC & SP full body phototherapy cabinet performance data is the same as or very similar to that of the claimed predicate device. The ultraviolet light tubes and cabinet construction used in the production of the predicate device and the 3 Series PC & SP device are the same.

Conclusion:

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the 3 Series PC & SP full body phototherapy cabinet 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 17 2007

The Daavlin Distributing Company
% Ms. Tara Mansur
Management Representative
205 West Bement Street
P.O. Box 626
Bryan, Ohio 43506

Re: K063621
Trade/Device Name: 3 Series PC & SP Phototherapy Cabinet
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: November 16, 2006
Received: December 5, 2006

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.

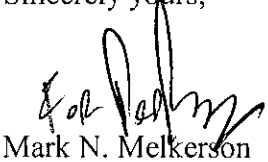
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Office of Compliance at (240) 276-0115. 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 (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

K063621

Indication for Use

510(k) Number

Device Name 3 Series PC & SP Phototherapy Cabinet

Indications for Use

The 3 Series PC & SP, full body phototherapy device, is a medical ultraviolet cabinet, which is intended 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

510(k) Number K063621