K 082731

DEC 17 2008

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
Address:	205 West Bement Street Bryan, Ohio 43506
Telephone:	419.636.6304
Contact:	David W. Swanson
Date Prepared:	September 11, 2008
Device Trade Name:	ML24000 UVA-1 Phototherapy Unit
Device Common Name:	UVA-1 Ultraviolet Full Body 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 3 Series PC & SP Phototherapy Cabinet Ultraviolet Phototherapy Cabinet K063621

Daavlin Distributing Company

Flex Controlled Phototherapy Equipment

3 Series X

Ultraviolet Phototherapy Cabinet

K050695

Device Description:

The ML24000 UVA-1 Phototherapy Unit is a microprocessor controlled full body ultraviolet light source, with spectral output at peak wavelengths of 370-390 nm. It is intended for use by or under the direction of a physician, for the treatment of atopic dermatitis (eczema). The desired dose is selected using the operator interface located on the front panel of the device. The ML24000 UVA-1 Phototherapy Unit delivers full body phototherapy, whereby Philips CLEO HPA 1018 Medium Pressure Lamps, which surround the patient, deliver the specified dose of UVA-1.

Predicate Device Comparison:

The ML24000 UVA-1 Phototherapy Unit is constructed in the same design configuration as the predicate devices, utilizing similar energy sources (UV lamps) and materials of similar and/or identical composition. The ML24000 UVA-1 Phototherapy Unit varies from the predicate device, in that the UV lamps used in the ML24000 device have a peak wavelength of 365nm, instead of a peak wavelength of 350nm. Specifically, on the Predicate Device, the output spectrum is 320-400nm with a peak at 350nm, and the ML24000 has an output spectrum of 340nm to 400nm with a peak at 365nm. The intended use, general and specific indications for use, mode of operation, labeling, treatment area, and general operating principals of the ML24000 UVA-1 Phototherapy Unit are the same or similar to those of the predicate device.

Intended Use:

The ML24000 UVA-1 Phototherapy Unit is a medical ultraviolet light source, which is intended for use by or under the direction of a licensed physician for the treatment of atopic dermatitis (eczema) on all skin types (I – VI).

Performance Data:

The ML24000 UVA-1 Phototherapy Unit performance data is the same as or very similar to that of the claimed predicate devices. The UV lamps and cabinet construction used in the production of the predicate device and the ML24000 UVA-1 Phototherapy Unit are similar.

Conclusion:

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the ML24000 UVA-1 Phototherapy Unit is substantially equivalent to the legally commercialized predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Daavlin Distributing Company
% Ms. Tara Mansur
Regulatory Affairs Coordinator
205 West Bement Street
P.O. Box 626
Bryan, Ohio 43506

DEC 17 2008

Re: K082731
Trade/Device Name: ML24000 UVA-1 Phototherapy Unit
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: September 12, 2008
Received: September 18, 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 K082731

Device Name ML24000 UVA-1 Phototherapy Unit

Indications for Use

The ML24000 UVA-1 Phototherapy Unit is a full body medical ultraviolet device, which is intended for the treatment of 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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