FEB 2 2 2011

K103708

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:	Michele Thiel
Date Prepared:	September 28, 2010
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 1 Series Phototherapy Cabinet Ultraviolet Phototherapy Cabinet K0100378

National Biological corporation

Houva III Phototherapy System

With PhotoSense II Exposure Control

K041212

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 diagnosed skin disorders. 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 HOUVA 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 Houva 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 1-series predicate device has lamps with a spectral peak at 365nm, exactly the same as the ML24000. 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 therapeutic treatment for individuals who require ultraviolet or visible radiation for diagnosed skin disorders.

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

The Daavlin Distributing Company
% Ms. Michele Thiel
Regulatory Affairs Coordinator
205 West Bement Street
Bryan, Ohio 43506

FEB 22 2011

Re: K103708
Trade/Device Name: ML24000 UVA-1 Phototherapy Unit and MED Test Kit
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: February 09, 2011
Received: February 14, 2011

Dear Ms. Thiel:

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,

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

Enclosure

Indication for Use

510(k) Number

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 use, by or under the direction of a physician, for therapeutic treatment for individuals who require ultraviolet or visible radiation for diagnosed skin disorders.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103708