



Food and Drug Administration
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September 10, 2015

Daavlin Distributing Company
Ms. Michele Thiel
Management Representative
205 West Bement Street, P.O. Box 626
Bryan, Ohio 43506

Re: K151795

Trade/Device Name: ML24000 PC UVA-1 Phototherapy Unit
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: July 16, 2015
Received: August 12, 2015

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151795

Device Name

ML24000 PC UVA-1 Phototherapy Unit

Indications for Use (Describe)

The ML24000 PC 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K. 510(k) Summary

Date of Summary: June 26, 2015

510(k) Submitter: Daavlin Distributing Company

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Trade Name: ML24000 PC UVA-1 Phototherapy Unit

Common Name: UVA-1 Ultraviolet Full Body Phototherapy Unit

Regulation Number: 21 CFR 878.4630

Classification Name: Ultraviolet lamp for dermatologic disorders

Device Class: Class II

Product Code: FTC

Panel: General and Plastic Surgery

Predicate Device: ML24000 UVA-1 Phototherapy Unit

510(k) Number: K103708

Product Code: FTC

Company: Daavlin Distributing Company

Device Description: The ML24000 PC 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. The ML 24000 PC UVA-1 Phototherapy Unit delivers a 360 degree full body treatment, with spectral output at peak wavelengths of 370-390 nm, through an array of 24 metal halide lamps in conjunction with a filtering system that absorbs infrared output and eliminated emissions below 320 nm. The 24 metal halide lamps are arranged in a four column modular design containing six lamps in each column.

Treatments are controlled through the Soft Touch Software interface. Access to this interface and stored information is restricted to individuals who have been established by the physician as authorized operators. Authorized operators program treatments in joules based on established treatment protocols governed by the patient’s skin type, condition, minimum erythral dose (M.E.D.), and treatment frequency.

Indications for Use: The ML24000 PC 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.

Predicate Comparison: The modified ML24000 PC UVA-1 Phototherapy Unit and the unmodified device are identical in nearly every aspect except for the incorporation of our Smart Touch Control System. Both the modified ML24000 PC UVA-1 Phototherapy Unit and the unmodified device are constructed using identical manufacturing methods, quality control operations, and are comprised of materials, components, and subassemblies which are identical or very similar in construction and composition. The modified ML24000 PC UVA-1 Phototherapy Unit and the unmodified device feature the same indications for use, patient population, application environment, lamp quantity, spectral output, labeling, treatment area, electrical requirements, ventilation requirements and device dimensions.

As previously stated the only difference between the modified ML24000 PC UVA-1 Phototherapy Unit and the unmodified device is in regards to the incorporation of our Smart Touch Control System. Our Smart Touch control system has been safely used in a closely related, legally marketed full body phototherapy unit (3 Series PC & SP Phototherapy Cabinet, K063621, 01/17/2007) which shares an identical classification regulation (CFR 878.4630), Product Code (FTC), significantly similar indications for use, and has been in commercial distribution since 01/17/2007. Beyond this modification there has been **no other changes** between the ML24000 PC UVA-1 Phototherapy Unit and the unmodified device

Features	Subject Device	Predicate Device
		ML24000 PC UVA-1 Phototherapy Unit
510(k) Number	This Submission	K103708

Indications for Use	The ML24000 PC 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.	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.
Prescriptive	Yes	Yes
Patient Population	Pediatric to Geriatric	Pediatric to Geriatric
Patient Contact	There is no direct patient contact with the device during treatment – Areas of skin are exposed to controlled ultraviolet radiation from a distance of approximately 9 inches (22.86 cm) away.	There is no direct patient contact with the device during treatment – Areas of skin are exposed to controlled ultraviolet radiation from a distance of approximately 9 inches (22.86 cm) away.
Anatomical Sites	Full Body	Full Body
Application Environment	Hospital, Clinic, Medical Center, Private Medical Practice, or Other Professional Medical Environments under direction of physician	Hospital, Clinic, Medical Center, Private Medical Practice, or Other Professional Medical Environments under direction of physician
Dimensions	Height : 98" (249cm) Width : 49" (125 cm) Depth : 62" (158 cm)	Height : 98" (249cm) Width : 49" (125 cm) Depth : 62" (158 cm)
Power	230V, 3~, 60Hz, 100A	230V, 3~, 60Hz, 100A
Ventilation Requirements	Minimum: 500 cfm Desired: 2000 cfm	Minimum: 500 cfm Desired: 2000 cfm
Spectral Output	370-390 nm	370-390 nm
Materials	Interior: Assembles components, ballasts, electronics housed in a metal frame with reflective internal surfaces, fluorescent lamps, and protective acrylic and filter glass.	Interior: Assembles components, ballasts, electronics housed in a metal frame with reflective internal surfaces, fluorescent lamps, and protective acrylic and filter glass.
	Exterior: Powder Coated Metal Casing	Exterior: Powder Coated Metal Casing
Lamp Quantity	24	24
Manufacturing Methods	Identical	Identical

Performance Standards:

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

Conclusion:

In summary, the modified ML24000 PC UVA-1 Phototherapy Unit described in this submission is, in our opinion, substantially equivalent to the legally commercialized unmodified predicate device.