



June 22, 2021

Daavlin Distributing Co.  
Michele Thiel  
Senior Regulatory Affairs Specialist  
205 W. Bement Street  
Bryan, Ohio 43506

Re: K210881

Trade/Device Name: M Series Phototherapy Equipment  
Regulation Number: 21 CFR 878.4630  
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders  
Regulatory Class: Class II  
Product Code: FTC  
Dated: March 22, 2021  
Received: March 25, 2021

Dear Michele 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya  
Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K210881

Device Name

M Series Phototherapy Equipment

Indications for Use (Describe)

The M Series Phototherapy Devices are indicated for use to treat diagnosed skin disorders such, as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The physician will determine the light spectrum (ultraviolet to visible), the energy or duration of the treatment, as well as the treatment environment. The population may range from pediatric, when accompanied by a responsible adult to operate it, to geriatric.

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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K210881  
**510(K) Summary:**

Date of Summary:	March 22, 2021
510(k) Submitter:	Daavlin Distributing Company
Contact Person:	<p>Michele Thiel</p> <p>Senior Regulatory Specialist/Management Representative</p> <p>Daavlin Distributing Company</p> <p>205 West Bement Street</p> <p>P.O. Box 626</p> <p>Bryan, Ohio 43506</p> <p>Phone: (419) 636-6304 Ext. 207</p> <p>Fax: (419) 636-1739</p> <p>Email: mthiel@daavlin.com</p>
Trade Name:	M Series Phototherapy Equipment
Common Name:	Phototherapy Equipment
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 Devices:	ClearLink Controlled Phototherapy Equipment & 1 Series Phototherapy Unit
510(k) Numbers:	K182215 & K100378
Product Code:	FTC
Company:	Daavlin Distributing Company
Device Description:	<p>The M Series Phototherapy Devices are intended to be used as a partial body therapeutic device. They are designed to be used under the direction of a physician for individuals who require phototherapy.</p> <p>Treatments are controlled through the ClearLink Software interface or the Smart Touch Software interface. Access to the interface and stored information is restricted to individuals who have been established by the physician as authorized operators. Authorized operators program treatments in joules or millijoules based on established treatment protocols governed by the patient's skin type, condition, minimum erythema dose (M.E.D.), and treatment frequency.</p>

Indications for Use:	The M Series Phototherapy Devices are indicated for use to treat diagnosed skin disorders such, as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The physician will determine the light spectrum (ultraviolet to visible), the energy or duration of the treatment, as well as the treatment environment. The population may range from pediatric, when accompanied by a responsible adult to operate it, to geriatric.
Intended Use:	The M Series Phototherapy Devices are intended to be used as a partial body therapeutic device. They are designed to be used under the direction of a physician for individuals who require phototherapy.
Predicate Comparison:	The M Series phototherapy equipment is constructed in the same design configuration as the predicate devices, utilizing identical energy sources and materials of identical or similar composition. The spectral output, mode of operation, labeling, treatment area, treatment modality, patient safety, and general operating principals of the M Series phototherapy equipment are the same or similar to those of the predicate devices. The only difference between the predicate devices and the M Series phototherapy device is the updated indication for use and intended use.

Features	Subject Device	Predicate Device	Predicate Device
	M Series Phototherapy Equipment	1 Series Phototherapy Unit	ClearLink Phototherapy Equipment
510(k) Number	<b>This Submission</b>	<b>K100378</b>	<b>K182215</b>
Indications for Use	<p>The M Series Phototherapy Devices are indicated for use to treat diagnosed skin disorders such, as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The physician will determine the light spectrum (ultraviolet to visible), the energy or duration of the treatment, as well as the treatment environment. The population may range from pediatric, when accompanied by a responsible adult to operate it, to geriatric.</p>	<p>The 1 Series Unit is a therapeutic product designed for individuals who require ultraviolet radiation for diagnosed skin disorders. The 1 Series, equipped with PL-L36W/03 Blue lamps, is indicated for the treatment of mild to moderate acne vulgaris.</p>	<p>The ClearLink Controlled Phototherapy Equipment are medical ultraviolet devices, which are intended for use, by or under the direction of a physician, for therapeutic treatment for individuals who require ultraviolet radiation for diagnosed skin disorders. When equipped with blue lamps the ClearLink Controlled Phototherapy Equipment is intended for use for the treatment of mild to moderate acne vulgaris.</p>
Prescriptive	Yes	Yes	Yes
Patient Population	Pediatric to Geriatric	Dermatology Patients	Pediatric to Geriatric
Patient Contact	<p>Patient comes in direct contact with the acrylic when placing hands or feet inside for treatment.</p>	<p>There is no direct patient contact required during treatment, but if prescribed patient can place hands directly on the acrylic.</p>	<p>There is no direct patient contact with the device during treatment – Areas of skin are exposed to controlled ultraviolet and blue lamp radiation from a distance of approximately 9 inches (22.86 cm) away.</p>
Anatomical Sites	Topical skin treatment	Topical skin treatment	Topical skin treatment

Features	Subject Device	Predicate Device	Predicate Device
	M Series Phototherapy Equipment	1 Series Phototherapy Unit	ClearLink Phototherapy Equipment
510(k) Number	This Submission	K100378	K182215
Application Environment	Hospital, Clinic, Medical Center, Private Medical Practice, or other environment under the direction of a physician.	Medical Office or under direction of physician	Hospital, Clinic, Medical Center, Private Medical Practice, or Other Professional Medical Environments under direction of physician
Materials	Assembled components housed in metal frame with reflective internal surfaces and fluorescent lamps	Assembled components housed in plastic case	Assembled components housed in metal frame with reflective internal surfaces and fluorescent lamps
Manufacturing Methods	Identical	Identical	Identical

Performance Standards:	The M Series phototherapy equipment performance data is the same as or very similar to that of the claimed predicate device. The lamps and construction used in the production of the predicate devices and the M Series phototherapy equipment are the same. The only difference between the predicate devices and the M Series devices is the updated indication for use and intended use. The rest of the devices (materials, construction, treatment modality, patient safety, etc., remains exactly the same or similar.
Conclusion:	On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the M Series phototherapy equipment is substantially equivalent to the legally commercialized predicate device.