November 4, 2021

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

Re: K212510
Trade/Device Name: 7 Series Phototherapy Device
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: August 9, 2021
Received: August 10, 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/pmn.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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212510

Device Name
7 Series Phototherapy Device

Indications for Use *(Describe)*
The 7 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 population may range from pediatric 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) Summary: K212510

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| Date of Summary: | November 2, 2021 |
| 510(k) Submitter: | Daavlin Distributing Company |
| Contact Person: | Michele Thiel<br>Senior Regulatory Specialist/Management Representative<br>Daavlin Distributing Company<br>205 West Bement Street<br>P.O. Box 626<br>Bryan, Ohio 43506<br>Phone: (419) 636-6304 Ext. 207<br>Fax: (419) 636-1739<br>Email: mthiel@daavlin.com |
| Trade Name: | 7 Series Phototherapy Device |
| 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 Phototherapy Equipment |
| 510(k) Numbers: | K182215 |
| Product Code: | FTC |
| Company: | Daavlin Distributing Company |
| Device Description: | The 7 Series Phototherapy Equipment is a partial-body, ultraviolet light source emitting phototherapy panel. The physician will determine the light spectrum (ultraviolet to visible), the energy or duration of the treatment, as well as the treatment environment. Its nominal size ranges from a 4 lamp no door; 74.5 In X 20 In X 24 In, 75 lbs (189.2 cm X 50.8 cm X 61 cm, 34 kg) to a 12 lamp with doors open; 74.5 In X 39.5 In X 24 In, 129 Lbs. (189.2 cm X 100.3 cm X 61 cm, 58.5 Kg) that is controlled by either an integrated digital timer with an LCD segmented display and four membrane buttons as the interface (the Flex Controller) or a microprocessor controller with an LCD touch screen display (the ClearLink Controller). When the operator sets the treatment time or the desired dose using the operator interface located on the control panel, the treatment begins by illuminating the lamps which emit the prescribed light. The treatment area consists of 4, 6, 8, 10, or 12 100-watt lamps and reflective surfaces configured in a panel. The patient stands in front of the panel during treatment. |

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| Indications for Use: | The 7 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 population may range from pediatric to geriatric. |
| Intended Use: | The 7 Series Phototherapy Equipment is 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 7 Series phototherapy equipment is constructed in the same design configuration as the predicate device, 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 7 Series phototherapy equipment is the same or similar to those of the predicate device. |

| **Features** | **Subject Device** | **Predicate Device** |
|---|---|---|
| | **7 Series Phototherapy Equipment** | **ClearLink Phototherapy Equipment** |
| **510(k) Number** | **This Submission K212510** | **K182215** |
| **Indications for Use** | The 7 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 population may range from pediatric to geriatric. | 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.<br>When equipped with blue lamps the ClearLink Controlled Phototherapy Equipment is intended for use for the treatment of mild to moderate acne vulgaris. |
| **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 lamp 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 and blue lamp radiation from a distance of approximately 9 inches (22.86 cm) away. |

| Features | Subject Device | Predicate Device |
|---|---|---|
| | **7 Series Phototherapy Equipment** | **ClearLink Phototherapy Equipment** |
| **510(k) Number** | **This Submission** | **K182215** |
| **Anatomical Sites** | Topical skin treatment | Topical skin treatment |
| **Application Environment** | Hospital, Clinic, Medical Center, Private Medical Practice, or other environment under the direction of a 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 metal frame with reflective internal surfaces and fluorescent lamps |
| **Manufacturing Methods** | Identical | Identical |

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| Performance Standards: | The 7 Series phototherapy equipment performance data is the same as or very similar to that of the claimed predicate devices. The lamps and construction used in the production of the predicate devices and the 7 Series phototherapy equipment are the same. The devices materials, construction, treatment modality, patient safety, etc., is exactly the same or similar. |
| Conclusion: | On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the 7 Series phototherapy equipment is substantially equivalent to the legally commercialized predicate device. |