December 13, 2023

Daavlin Distributing Co.
Michele Thiel
Regulatory Manager
205 West Bement Street
Bryan, Ohio 43506

Re: K233811
Trade/Device Name: DT Controlled Phototherapy Equipment
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: November 29, 2023
Received: November 29, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2023.12.13 16:38:26 -05'00'

For Tanisha Hithe
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)*
K233811

Device Name
DT Controlled Phototherapy Equipment

Indications for Use *(Describe)*
The DT Controlled Phototherapy Equipment 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)

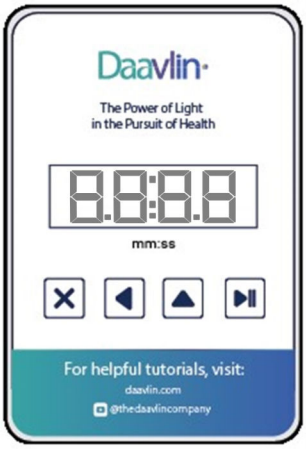
CONTINUE ON A SEPARATE PAGE IF NEEDED.

Special 510k Summary

510(K) Summary:

Date of Summary:	November 28, 2023
510(k) Submitter:	Daavlin Distributing Company
Contact Person:	Michele Thiel Regulatory Manager Daavlin Distributing Company 205 West Bement Street P.O. Box 626 Bryan, Ohio 43506 Phone: (419) 636-6304 Ext. 207 Fax: (419) 636-1739 Email: mthiel@daavlin.com
Trade Name:	DT Controlled Phototherapy Equipment
Common Name:	Phototherapy Equipment
510(k) Number:	K233811
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:	Dermapal, 1 Series Phototherapy Equipment
510(k) Number:	K073587, K220840
Company:	Daavlin Distributing Company
Device Description:	The DT Controller is a modernization of the DermaPal Controller (510(k) K073587). Like its predicate, the DT Controller is designed to turn a phototherapy device on and off based on time. It is designed to be installed in a wider family of devices. It uses the same 4 button UI with a larger backlit screen for better readability and is based on a more commercially available PIC16 processor. A modification to the way a prescription is entered was done to harmonize the process across different devices.
Indications for Use:	The DT 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.
Intended Use:	The DT Controlled Phototherapy Equipment 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.

Predicate Comparison:	The DT controlled phototherapy equipment is constructed in the same design configuration as the predicate device, utilizing identical energy sources (UV lamps) and materials of identical composition. The DT controlled devices vary from the predicate device, in that the control system hardware and software of the DT control has been updated to utilize current technology. The intended use, general and specific indications for use, spectral output, mode of operation, labeling, treatment area, and general operating principles of the DT controlled equipment are the same or similar to those of the predicate devices. Functional testing in the form of Black Box testing was completed on the DT controller and the functions appear to be working per the specifications.

Features	**Subject Device** **DT Controlled Phototherapy Equipment**	**Predicate Device** **Dermapal**	**Predicate Device** **1 Series Controlled Phototherapy Equipment**
510(k) Number	**This Submission**	**K073587**	**K220840**
Picture			
Indications for Use	The DT Controlled Phototherapy Equipment 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 for use, by or under the direction of a physician, for the treatment of localized cases of psoriasis and vitiligo.	The 1 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.
Prescriptive	Yes	Yes	Yes
Patient Population	Pediatric to Geriatric	Dermatology Patients	Pediatric to Geriatric

Features	Subject Device	Predicate Device	Predicate Device
	DT Controlled Phototherapy Equipment	Dermapal	1 Series Controlled Phototherapy Equipment
510(k) Number	This Submission	K073587	K220840
Patient Contact	The DT Controlled Phototherapy Equipment device is designed have the areas of skin to be exposed to controlled lamp radiation by placing the area on the Acrylic, or from a distance of approximately 9 inches (22.86 cm) away.	N/A	The 1 Series device is designed have the areas of skin to be exposed to controlled lamp radiation by placing the area on the Acrylic, or from a distance of approximately 9 inches (22.86 cm) away.
Anatomical Sites	Topical skin treatment	Topical local skin treatment	Topical skin treatment
Application Environment	Hospital, Clinic, Medical Center, Private Medical Practice, or other environment under the direction of a physician.	N/A	Hospital, Clinic, Medical Center, Private Medical Practice, or other environment under the direction of a physician.
Materials	Face of the controller is a plastic overlay. The controller is a PC Board populated with the processors, power supply, display and other standard electronic parts.	Assembled components housed in plastic case	Assembled components housed in plastic frame with reflective internal surfaces and fluorescent lamps
Manufacturing Methods	Identical	N/A	Identical

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