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

October 29, 2018

Re: K182215
Trade/Device Name: ClearLink Controlled Phototherapy Equipment
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp for Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: August 13, 2018
Received: August 15, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S
2018.10.29 09:04:00 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182215

Device Name
ClearLink Controlled Phototherapy Equipment

Indications for Use *(Describe)*
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.

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.

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E. 510(K) Summary:

Date of Summary:	October 26, 2018
510(k) Submitter:	Daavlin Distributing Company
Contact Person:	Michele Thiel Management Representative 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:	ClearLink Controlled Phototherapy Equipment
510(K) Number:	K182215
Common Name	Ultraviolet 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:	Flex Controlled Phototherapy Equipment & 1 Series
510(k) Numbers:	K050695 & K100378
Product Code:	FTC
Company:	Daavlin Distributing Company

Device Description:	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. The ClearLink Phototherapy Equipment delivers treatment, with Narrow Band UVB, Broad Band UVB and/or UVA ultraviolet light. Treatments are controlled through the ClearLink 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 erythemal dose (M.E.D.), and treatment frequency.
Indications for Use:	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.
Predicate Comparison:	The ClearLink 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 ClearLink controlled devices vary from the predicate device, in that the control system hardware and software of the ClearLink 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 principals of the ClearLink controlled equipment are the same or similar to those of the predicate device. The only difference between the predicate flex devices and the link devices is the substitution of the link controller for the flex controller for actual entry of doses. The rest of the devices (materials, construction, treatment modality, patient safety, etc., remains exactly the same.

Features	Subject Device	Predicate Device
	ClearLink Phototherapy Equipment	Flex Controlled Phototherapy Equipment
510(k) Number	This Submission	K050695 & K100378
Indications for Use	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.	The Flex Controlled Phototherapy Equipment are ultraviolet emitting medical light sources, which are intended for use by or under the direction of a licensed physician for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I-VI). When equipped with blue lamps the Series-1 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 ultraviolet and blue 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 radiation from a distance of approximately 9 inches (22.86 cm) away.
Anatomical Sites	Topical skin treatment	Topical skin treatment
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
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

Performance Standards:	The ClearLink controlled phototherapy equipment performance data is the same as or very similar to that of the claimed predicate device. The ultraviolet light tubes and cabinet construction used in the production of the predicate device and the ClearLink controlled phototherapy equipment are the same. The only difference between the predicate flex devices and the link devices is the substitution of the link controller for the flex controller for actual entry of doses. 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 ClearLink controlled phototherapy equipment is substantially equivalent to the legally commercialized predicate device.