March 24, 2023

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

Re: K230382
Trade/Device Name: 3 Series NeoLux
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: March 16, 2023
Received: March 16, 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 (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,

Jessica Carr -S

for Jianting Wang
Acting 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)*
K230382

Device Name
3 Series NeoLux

Indications for Use *(Describe)*
The 3 Series Neolux 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)

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K230382 510(k) Summary

510(K) Summary:

Date of Summary:	March 23, 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:	3 Series NeoLux
Common Name:	Phototherapy Equipment
510(k) Number:	K230382
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:	3 Series Phototherapy Unit (K153749) M Series Phototherapy Equipment (K210881)
510(k) Numbers:	K153749, K210881
Company:	Daavlin Distributing Company

Device Description:	The 3 Series NeoLux device 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 3 Series NeoLux device delivers a 360-degree full body treatment, with spectral output from UV through visible, through an array of 24-48 fluorescent lamps (Either F72 or F79 length). Treatments are controlled through the Smart Touch Controller Software interface, Flex Controller or ClearLink Controller interface. The Smart Touch Software interface is installed remotely on a custom-built computer. An "off the shelf' replacement is not possible. Replacement can only be obtained through Daavlin. Access to the interface and stored information is restricted to individuals who have been established by the physician as authorized operators. Furthermore, the physician can restrict the amount and type of access that is granted to each authorized operator. Each authorized operator is assigned an initial default pin number. The system requires each operator to select a new individual pin and change the default pin upon initial logon. 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. The Smart Touch equipped computer will interface with the 3 Series NeoLux device through a closed wired Ethernet connection and a Daavlin Distributing Company UV4001. While the Flex Controller is controlled by an integrated digital timer with an LCD segmented display and four membrane buttons as the interface, and ClearLink Controller is controlled by a microprocessor controlled with an LCD touch screen display. 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.
Indications for Use:	The 3 Series Neolux 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 3 Series Neolux devices are intended to be used as full body therapeutic devices. They are designed to be used under the direction of a physician for individuals who require phototherapy.

Predicate Comparison:	The 3 Series NeoLux device 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 3 Series NeoLux device is the same or similar to those of the predicate devices.

Features	**Subject Device**	**Predicate Device**	**Predicate Device**
	3 Series NeoLux Phototherapy Equipment	**3 Series NeoLux Phototherapy Unit**	**M Series Phototherapy Equipment**
510(k) Number	**This Submission K230382**	**K153749**	**K210881**
Picture			

Features	Subject Device	Predicate Device	Predicate Device
	3 Series NeoLux Phototherapy Equipment	3 Series NeoLux Phototherapy Unit	M Series Phototherapy Equipment
510(k) Number	This Submission K230382	K153749	K210881
Indications for Use	The 3 Series Neolux 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 3 Series NeoLux is a full body ultraviolet emitting medical light source, which is 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).	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.
Prescriptive	Yes	Yes	Yes
Patient Population	Pediatric to Geriatric	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.	Patient comes in direct contact with the acrylic when placing hands or feet inside for treatment.
Anatomical Sites	Topical skin treatment	Topical skin treatment	Topical skin treatment

Features	Subject Device	Predicate Device	Predicate Device
	3 Series NeoLux Phototherapy Equipment	3 Series NeoLux Phototherapy Unit	M Series Phototherapy Equipment
510(k) Number	**This Submission K230382**	**K153749**	**K210881**
Application Environment	Hospital, Clinic, Medical Center, Private Medical Practice, or other Professional Medical environments under the direction of a physician.	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 environment under the direction of a physician.
Materials	Interior: Assembles components, ballasts, electronics housed in a metal frame with reflective internal surfaces, fluorescent lamps, and protective acrylic.	Interior: Assembles components, ballasts, electronics housed in a metal frame with reflective internal surfaces, fluorescent lamps, and protective acrylic.	Assembled components housed in metal frame with reflective internal surfaces and fluorescent lamps
Manufacturing Methods	Identical	Identical	Identical
Number of Lamps	24 - 48	24 - 48	8
Lamp Spectrums	UV through Visible	UV through Visible	UV through Visible
Treatment Area	Full Body	Full Body	Partial Body
Patient Cooling	Fan	Fan	Ambient
Power Output (mW/cm^2)	5 – 25[4]	5 – 25[5]	2.9- 17.4[6]
Controller	ClearLink Controller Flex Controller SmartTouch Controller	Flex Controller SmartTouch Controller	ClearLink Controller SmartTouch Controller

[4] Power output is dependent on number of lamps at 9".
[5] Power output is dependent on number of lamps at 9".
[6] Power output is dependent on number of lamps at 0".

Performance Standards:	The 3 Series NeoLux device 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 3 Series NeoLux 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 3 Series NeoLux device is substantially equivalent to the legally commercialized predicate devices.