DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 30, 2016

Daavlin Distributing Company
Ms. Michele Thiel
Management Representative
205 West Bement Street
Bryan, Ohio 43506

Re: K153749
Trade/Device Name: 3 Series Phototherapy Unit
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: June 1, 2016
Received: June 1, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153749

Device Name
3 Series NeoLux Phototherapy Unit

Indications for Use *(Describe)*
The 3 Series NeoLux, full body phototherapy device, is a medical ultraviolet cabinet, which is intended for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

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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K. 510(k) Summary

Date of Summary:	December 14, 2015
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:	3 Series NeoLux Phototherapy Unit
Common Name	Ultraviolet Full Body Phototherapy Unit
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 Device:	3 Series SP/PC Phototherapy Unit
510(k) Number:	K063621
Product Code:	FTC
Company:	Daavlin Distributing Company

Device Description: The 3 Series NeoLux Phototherapy Unit 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 radiation for diagnosed skin disorders. The 3 Series NeoLux Phototherapy Unit delivers a 360 degree full body treatment, with spectral output at peak wavelengths of 311 nm (Narrow Band UVB) and/or 350 nm (UVA), through an array of 24-48 fluorescent lamps.

Treatments are controlled through the Soft Touch 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 3 Series NeoLux, full body phototherapy device, is a medical ultraviolet cabinet, which is intended for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

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Predicate Comparison: The 3 Series NeoLux Phototherapy Unit and the 3 Series SP/PC device are identical in nearly every aspect. Both the 3 Series NeoLux and the 3 Series SP/PC device are constructed using identical manufacturing methods, quality control operations, and are comprised of materials, components, and subassemblies which are identical or very similar in construction and composition. The 3 Series NeoLux Phototherapy Unit and the 3 Series SP/PC device feature the same indications for use, patient population, application environment, lamp types, spectral output, labeling, treatment area, electrical requirements, and ventilation requirements.
As previously stated the only difference between the 3 Series NeoLux Phototherapy Unit and the 3 Series SP/PC predicate device are changes in exterior cosmetics and lamp covering. Beyond this modification there has been **no other changes** between the 3 Series NeoLux Phototherapy Unit and the 3 Series SP/PC predicate device

Features	Subject Device	Predicate Device
	3 Series NeoLux Phototherapy Unit	**3 Series SP/PC Phototherapy Unit**
510(k) Number	This Submission	K063621
Indications for Use	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 3 Series PC & SP, full body phototherapy device, is a medical ultraviolet cabinet, which is itended for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I-VI)
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 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	Full Body	Full Body
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
Dimensions	Height : 83.6" (212.3cm) Width : 41.4" (104.4 cm) Depth : 39.3" (99.8 cm)	Height : 84" (213cm) Width : 42" (106 cm) Depth : 41" (104 cm)
Power	208-240V, 60Hz, 100A	208-240V, 60Hz, 100A
Ventilation Requirements	Minimum: XXX cfm Desired: XXX cfm	Minimum: XXX cfm Desired: XXX cfm
Spectral Output	280-400 nm	280-400 nm
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 metal grids.
	Exterior: Metal and Plastic Casing	Exterior: Metal and Plastic Casing
Lamp Quantity	Up to 48 F72 or F79 UVB or UVA	Up to 48 F72 UVB or UVA
Manufacturing Methods	Identical	Identical

Performance Standards:	The 3 Series NeoLux Phototherapy Unit performance data is the same as or very similar to that of the claimed predicate device. The ultraviolet lamps and cabinet construction used in the production of the predicate device and the 3 Series NeoLux Phototherapy Unit are the same.
Non-clinical Testing:	Performance testing for conformance to IEC 60601-1-2:2007; IEC 60601-1:2012; IEC 60601-2-57:2011 EMC and Safety.
Conclusion:	In summary, the 3 Series NeoLux Phototherapy Unit described in this submission is, in our opinion, substantially equivalent to the legally commercialized unmodified predicate device.