k100378

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

APR 28 2010

Submitter's Name: The Daavlin Distributing Company

Registration Number: 1526255

Address: 205 West Bement Street
Bryan, Ohio 43506

Telephone: 419.636.6304

Contact: Michele Thiel

Date Prepared: February 3, 2010

Device Trade Name: 1 Series Phototherapy Unit

Device Common Name: 1 Series Partial- Body Phototherapy Unit

Device Classification: Class II

Product Code: FTC

Regulation Number: CFR 878.4630

Regulation Name: Ultraviolet lamp for dermatologic/skin disorders

K100378

Predicate Device: Daavlin Distributing Company
Digital DermaPal®
K073587

Daavlin Distributing Company
Flex Controlled Phototherapy Equipment
K050695

National Biological Corporation
Panosol Tru-Blu Phototherapy System
K070934

DUSA Pharmaceuticals, Inc.
BLU-U, MODEL 4170
K031805

K100378

Device Description:

The 1 Series Unit is a partial-body phototherapy panel ultraviolet light source controlled by an integrated digital timer or a microprocessor controller. The operator interface consists of two main components: a LCD, and a Membrane with 4 buttons. 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 ultraviolet light or blue light. The spectral output peaks at wavelengths of 305nm,311nm,350nm,365nm, or 420nm depending on lamp. The 1 Series Unit is a therapeutic product designed for individuals who require ultraviolet radiation for diagnosed skin disorders or blue light radiation for acne vulgaris.

Predicate Device Comparison:

The 1 Series Unit is constructed in the same design configuration as the predicate device, utilizing identical energy sources (UV or blue light lamps) and materials of identical composition. The intended use, general and specific indications for use, spectral output, mode of operation, labeling, treatment area, and general operating principals of the 1 Series light emitting medical device are the same or similar to those of the predicate devices.

Intended Use:

The 1 Series Unit is a therapeutic product designed for individuals who require ultraviolet or blue light radiation for diagnosed skin disorders.

Performance Data:

The 1 Series Phototherapy Unit performance data is the same as or very similar to that of the claimed predicate devices. The UV or blue light lamps and cabinet construction used in the production of the predicate devices and the 1 Series Phototherapy Unit are similar.

Conclusion:

On the basis of the information provided in this Summary, the Daavlin Distributing Company believes the 1 Series Phototherapy Unit is substantially equivalent to the legally commercialized predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

The Daavlin Distributing Company
% Ms. Michele Thiel
205 West Bement Street
Bryan, Ohio 43506

APR 2 8 2010

Re: K100378
Trade/Device Name: 1 Series Phototherapy Unit
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: April 22, 2010
Received: April 22, 2010

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.

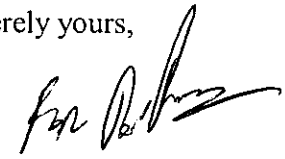
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Us

510(k) Number K100378

Device Name 1 Series Phototherapy Unit

Indications for Use

The 1 Series Unit is a therapeutic product designed for individuals who require ultraviolet radiation for diagnosed skin disorders. The 1-Series, equipped with PL-L36W /03 blue lamps, is indicated for the treatment of mild to moderate acne vulgaris

Prescription Use _X__ OR Over-the-Counter Use ___

(per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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