K103204

APR 2 7 2011

SOLARC SYSTEMS INC.

510(k) Summary

Date: Oct26, 2010

Trade Name: **Solarc / SolRx E-Series Ultraviolet Phototherapy Lamp Unit Family**

A new family of medical devices that can be used singly, or ganged together in any number and combination of models. The devices use various numbers and lengths of tubular ultraviolet fluorescent bulbs. The model numbering system for single devices is as follows:
Ehn0t-waveband-suffix , where:
E = A constant indicating the E-Series and standing for "Expandable".
h = The nominal height of the device in inches divided by ten; where h=2 for 24" (2-foot) high devices, h=4 for 48" (4-foot) high devices, h=7 for 72" (6-foot) high devices, and h=8 for 80" (2-metre) high devices.
n = The number of bulbs in the device; with the only exceptions being "9" for 10-bulb devices (such as E790), and "92" for 12-bulb devices (such as E792).
0 = A constant (zero); except for 12-bulb devices where this is a "2", such as the "E792".
t = The device type, either "**M**" for a "Master" device, or "**A**" for an "Add-on" device.
waveband = either "**UVBNB**" for UVB-Narrowband, "**UVB**" for UVB-Broadband, "**UVA**" for UVA, and "**UVA1**" for UVA-1.
suffix = any or all of: "**CR**" for Clinic Rated devices, "**AW**" for devices equipped with a clear Acrylic Window in lieu of wire guards, "**SD**" for reflective Side Doors and "**RB**" for internal Reflector Bulbs.

Common Name: Ultraviolet Phototherapy Lamp Unit

Classification: 21 CFR 878.4630, Product Code FTC

Intended Use: Phototherapeutic treatment of psoriasis, vitiligo, and atopic dermatitis (eczema)

Applicant: Solarc Systems Inc., 1515 Snow Valley Road, Minesing, ON, Canada L0L 1Y0
Contact: Bruce Elliott, P.Eng., President Solarc Systems Inc.
Phone: 705-739-3048 Fax: 705-739-9684 Email: **belliott@solarcsystems.com**

Solarc Systems Inc. declares that, to the best of its knowledge, the proposed device family has the same intended use and similar technical characteristics as the following predicate devices:

Solarc/SolRx 1000 Series [510(k)# K935572]
Solarc/SolRx 500 Series [510(k)# K031800]
Solarc/SolRx 100 Series [510(k)#: K061589]
Daavlin "7-Series" and "2-Series" [510(k)# K854498 "Spectra 724"]
National Biological Corp. (NBC) "Foldalite-32" [510(k)#: K827890]
National Biological Corp. (NBC) "Panosol 3D" [510(k)#: uncertain]
National Biological Corp. "Panosol II... with optional wings" [510(k)#: uncertain]

It can be demonstrated that the proposed device is as safe and effective as the legally marketed devices and does not raise different questions regarding safety and effectiveness than the predicate devices. This is based on the following areas of comparison between the proposed device and the referenced predicate devices:

Intended Use

As with all the predicate devices, the proposed device is intended for medical ultraviolet phototherapy delivered in the patient's home, at a physician's office or in a hospital's clinic; for the treatment of psoriasis, vitiligo, and eczema (atopic dermatitis).

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Design Concept
The proposed device is constructed primarily of sheet metal, and has provision for connecting additional lighting banks, as do two of the predicate devices.

Treatment Area & Anatomical Sites
The proposed device can be made in 2-foot, 4-foot, 6-foot and 2-metre lengths; for partial or full body treatment excluding the eyes, as are the predicate devices. The proposed device has provision for ultraviolet reflective side panel doors, as does at least one of the predicate devices. The treatment area of the proposed device can be reduced by using the "Face Shield" accessory, which is similar to the aperture plate system of the Solarc/SolRx 100 Series predicate device.

Type of Ultraviolet Bulbs
The proposed device uses low pressure mercury vapor fluorescent ultraviolet bulbs that are comparable to that of the predicate devices, as are the spectral distribution, irradiance levels, ballasts and related circuitry.

Quantity of Ultraviolet Bulbs
The proposed device uses 2 to 12 bulbs per device, or multiples thereof when devices are ganged together, within electrical current limits. The predicate devices use 1 to 48 bulbs.

Electrical Rating
The voltage and frequency ratings are comparable. High voltage breakdown, current leakage, and electro-magnetic compatibility specifications meet current industry and medical device standards.

Timer
The proposed device uses a digital countdown timer that is technically comparable to that of the predicate devices.

User's Manual
The User's Manual is written for the layman user and provides comprehensive exposure guidelines. It is at least as effective as the predicate devices.

Safety Features
The proposed device has a keyed switchlock or timer password entry to prevent unauthorized usage, wire guards or an acrylic window to reduce the chance of bulb breakage, and FDA compliant ultraviolet protective goggles; all comparable to one or more of the predicate devices.

Regulatory Requirements
The proposed device is designed and will be manufactured according to the FDA Good Manufacturing Practices and ISO13485. Solarc Systems Inc. is ISO-13485:2003 certified.

Conclusion
On the basis of the information provided, Solarc Systems Inc. believes that the proposed device is substantially equivalent to legally commercialized predicate devices.

End of 510(k) Summary

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

Solarc Systems Inc.
% Mr. Bruce Elliott
1515 Snow Valley Road
Minesing, Ontario
Canada L0L 1Y3

APR 27 2011

Re: K103204
Trade/Device Name: Solarc/SolRx E-Series Ultraviolet Phototherapy Lamp Unit Family and Accessories
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: April 11, 2011
Received: April 12, 2011

Dear Mr. Elliott:

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.

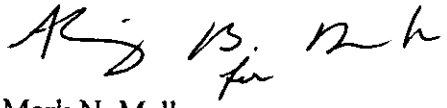
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use

510(k) Number (if known): **K103204**

Device Name: Solarc / SolRx E-Series Ultraviolet Phototherapy Lamp Unit Family

Indications for Use:

The Solarc/SolRx E-Series Ultraviolet Phototherapy Lamp Family is a wall-mounted or self-supporting ultraviolet phototherapy lamp unit used for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema). It is intended for use as a spot or full-body treatment device. It is intended for use on all skin types. (I –VI)

This device is intended for Prescriptive Use only, per Part 21 CFR 801 Subpart D.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

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

510(k) Number K103204