K031800 1/2

SOLARC SYSTEMS INC.

SEP 1 0 2003

510(k) Summary

Date:	June 8,2003
Device Name:	Solarc / SolRx 500 Series Ultraviolet Phototherapy Lamp Unit Family A new medical device family consisting of 5 models: 510UVB-NB, 520UVB-NB, 530UVB-NB, 540UVB-NB, 550UVB-NB
Common Name:	Ultraviolet Phototherapy Lamp Unit
Applicant:	Solarc Systems Inc., 12 Parker Court, Barrie, ON, Canada L4N 2A6
Contact:	Bruce Elliott, P.Eng., President Solarc Systems Inc.
Phone:	705-739-8279
Fax:	705-739-9684

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 predicate devices: National Biological Hand/Foot, and National Biological Panosol II 2 foot.

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:

Treatment Area & Anatomical Sites:
The proposed device can be used for both spot and hand & foot treatment, as can the predicate devices. The proposed device has a treatment area of approximately 2 square feet and is comparable to the predicate devices, with treatment areas of 3 to 4 square feet.

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 and irradiance levels. The ballasts and related circuitry are also comparable.

Electrical Rating
The voltage, frequency, current ratings and other electrical characteristics are comparable. High voltage breakdown and current leakage specifications meet current industry and medical device standards.

Digital Timer
The proposed device uses a digital 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.

K031960 4/2

SOLARC SYSTEMS INC.

Safety Features

The proposed device has a keyed switchlock to prevent unauthorized usage, wire bulb guards to reduce the chance of bulb breakage and FDA compliant ultraviolet protective goggles; all comparable to those of the predicate device. In addition, the proposed device has a removable hood to minimize light leakage when used for hand & foot treatments.

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 certified.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2003

Mr. Bruce Elliott, P. Eng.
President
Solarc Systems, Inc.
12 Parker Court
Barrie, Ontario
Canada L4N 2A6

Re: K031800
Trade/Device Name: Solarc/SolRx 500 Series
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: June 9, 2003
Received: June 12, 2003

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number K031800

Device Name: Solarc / SolRx 500 Series Ultraviolet Phototherapy Lamp Unit Family
A new medical device family consisting of 5 models:
510UVB-NB, 520UVB-NB, 530UVB-NB, 540UVB-NB, 550UVB-NB

The Solarc/SolRx 500 Series is an ultraviolet phototherapy lamp unit used for the physician prescribed treatment of psoriasis, vitiligo, atopic dermatitis (eczema). It is intended for use as a spot treatment device, or as a hand & foot device. It is intended for use on all skin types. (I –VI)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031800