K052660 OCT 17 2005

510(k) Summary

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

Date: September 26, 2005

Applicant: The Richmond Light Co., Inc., 2301 Falkirk Drive, Richmond, VA 23236

Contact: Alex M. Clarke, Ph.D.

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Device Name A family of 4 Home UV Phototherapy Sources consisting of the 672 BD Jordan Light©, and the three versions of the S2000 Series, ie., the S-2400, the S-2600, and the S-2800.

Common Name: Home UV Phototherapy Device

Device Classification: Class II

Product Code: FTC

Regulation Number: CFR 876.4630

Regulation Name: Ultraviolet lamp for dermatologic/skin disorders.

The Richmond Light Co., Inc, declares that, to the best of its knowledge, the proposed family has the same use and similar technical characteristics as the predicate devices: The Richmond Light Co., Inc. 648B (K812446), the National Biological Panasol 4 and 6 foot units (K904426, -27, -28), and the Daavlin Spectra 724 Series, Ultraviolet Phototherapy Device (K854498)

The submitted devices can be demonstrated to be as safe and effective as the legally marketed predicate devices and do not vary in any significant degree in the safety and effectiveness from the predicate devices, for instance:

1-Treatment Areas: The devices have the same area of intended treatment, being single shaped panels or a connected configuration of panels meant for half body (front/back or side/side) exposure.

2 -Ultraviolet bulbs: The devices use the same speciality fluorescent tubes manufactured with a quartz tube and suitable phosphor as the predicate devices. All tubes are from accredited manufacturers (Voltarc, Light Sources, Philips Lighting) designated FS-72 SL-UVB (in the 672B), FS-72-HO-UVB (S-2000 Series, Broad Band), FS-72 -TL-01and 100W/TL-01 [Philips Narrow Band] (S-2000 Series Narrow Band), and F-72-HO-UVA (S-2000 Series UVA). These tubes are available on prescription from The Richmond Light Co., Inc., Daavlin Distributing, and National Biological Co, as well as other phototherapy device manufacturers and distributors.

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3 -Electrical Rating.: The AC power requirements (Voltage and current) requirements are similar to the predicate units. Electrical components (with the exception of the digital timer) are all commercially available. All electrical components are Underwriters Laboratory listed.

4 -Digital Timer: The digital timer is manufactured to specifications supplied by The Richmond Light Company, has an exposure time range from 1 second to 9 minutes 59 seconds, is accurate to +/- 1 second, and is technically compatible to the timers in the predicate devices. The Digital Timer is UL Listed.

5 -Manuals: Manuals are supplied at two levels. A Physician's Technical Manual is supplied only to physicians, having all of the pertinent technical information and data for all of the units supplied by The Richmond Light Company to allow the physician to prescribe a suitable exposure time for the individual patient. Patient treatment manuals are supplied for Wide Band and Narrow Band UVB treatments separately, specific to the unit ordered. These, while not "talking down" to the patient, are meant to lead them by the hand through the setup of the unit and their treatment, specifically for psoriasis. The Richmond Light Co. feels these manuals are at least as effective as those of the predicate devices.

5 -Safety Features: As in the predicate devices, a keyswitch is provided to allow the owner to prevent unauthorized usage, wireguards protect the tubes to prevent the patient or others from accidentally coming into physical contact with the tubes, and FDA compliant ultraviolet goggles are supplied. Additionally, the Digital Timer emits audible "beeps" at 30 second intervals to aid the patient in keeping alert and monitoring the time of exposure. It also has a supplemental circuit to shut down the unit at 10 minutes.

6 -Regulatory Requirements: The submitted devices are designed and manufactured according to the FDA Good Manufacturing Practices..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Alex M. Clarke, Ph.D.
President
The Richmond Light Co., Inc.
2301 Falkirk Drive
Richmond, Virginia 23236

Re: K052660
Trade/Device Name: Model 672-BD, Home UVB Light Source (Jordan Light©)
Model 2400, 4 (6 foot) HO lamp Light Source
Model 2600, 6 (6 foot) HO lamp Light Source
Model 2600, 8 (6 foot) HO lamp Light Source
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: September 26, 2005
Received: September 28, 2005

Dear Dr. Clarke:

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 (240) 276-0115. 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/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Amended 05/10/11

Statement of Indications for Use:

510(k) Number (if know): ____**K052660**

Device Names:

Model 672-BD, Home UVB Light Source (Jordan Light©)

Model 2400, 4 (6 foot) HO lamp Light Source

Model 2600, 6 (6 foot) HO lamp Light Source

Model 2800, 8 (6 foot) HO lamp Light Source

All Models in this submission are phototherapy products designed for individuals who require specific Ultraviolet radiation therapy for the treatment of psoriasis..

Prescription Use: ___**X**_____ AND/OR Over-The Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052660