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MAR 15 2005

510(k) Summary of Safety and Effectiveness for the Photo Therapeutics Limited Omnilux Plus

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Photo Therapeutics Limited Station House Stamford New Road Altrincham Cheshire WA14 1EP United Kingdom
Contact Person:	Steve Hutson Director of Engineering and Regulatory Affairs Photo Therapeutics Limited Station House Stamford New Road Altrincham Cheshire WA14 1EP United Kingdom
Summary Preparation Date:	November 26th, 2004

2. **Names**

Device Name:	Omnilux Plus
Classification Name:	Lamp, Infrared Product Code: ILY Panel: 89

3. **Predicate Devices**

The Omnilux Plus is substantially equivalent to the following device:

Photonic Stimulator manufactured by Bales Scientific Inc (K974468)
Quantum Warp 10 manufactured by Quantum Devices Inc (K032229)
SuperNova manufactured by Light Force Therapy Inc (K022888)
Pain-X-2000 manufactured by DioMedics Inc (K0982546)
LightPatch/Spinal Pad manufactured by Bioscan Inc (K993684 & 5)

4. Device Description

The Omnilux Plus is a near infra-red light source of high spectral purity. It provides uniform or "hot-spot" free illumination. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength is 830 ± 5 nm. The Omnilux Plus base unit contains the power supplies and the control unit. Attached to the base unit are three folding arms. The LED head can be attached to the end of the arms and then positioned for patient treatment. The control unit consists of an LCD and keyboard together with the control electronics. The user interface software allows the operator to access and control all device functions.

5. Indications for Use

The Omnilux Plus is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

6. Performance Data

Based upon an analysis of the overall performance characteristics for the device, Photo Therapeutics Limited believes that no significant differences exist. Therefore, the Omnilux Plus raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2005

Mr. Steve Hutson
Director of Engineering and Regulatory Affairs
Photo Therapeutics Limited
Station House
Stamford New Road
Altrincham
Cheshire WA14 1EP

Re: K043317
Trade/Device Name: Omnilux Plus
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: February 7, 2005
Received: February 16, 2005

Dear Mr. Hutson:

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,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043317

Device Name Omnilux Plus

Indications for Use:

The Omnilux Plus is used for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

Prescription Use ✓ 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 ON 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 K043317