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510(k) Summary of Safety and Effectiveness for the Photo Therapeutics Limited Omnilux Revive and Blue Combination

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 17th, 2004

2. Names

Device Name: Omnilux Revive and Blue Combination

Classification Name:

Laser Instrument, Surgical powered
Product Code: GEX
Panel: 79

3. Predicate Devices

Predicates for the Omnilux Revive and Omnilux Blue were detailed in K030426 and K030883 respectively, but the predicates are listed below for completeness.

Omnilux Revive is substantially equivalent to ...
IPL Quantum SR manufactured by Lumenis, Inc. (K020839)
Aurora SR manufactured by Syneron Medical Ltd.(K022266)
EsteLux manufactured by Palomar Medical Technologies, Inc. (K020453)

Omnilux Blue is substantially equivalent to ...
Lumenis ClearLight (K013623).

4. Device Description

The Omnilux Revive and Blue is a combination of two sources of high spectral purity. They provide uniform or "hot-spot" free illumination. The two output are pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of Omnilux Revive is 633 ± 5 nm, and Omnilux Blue is 415 + 5nm. The Omnilux 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 Revive and Blue Combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

6. Performance Data

Based upon an analysis of the overall performance characteristics for the device, Photo Therapeutics Limited believes that no significant differences exist between the 'Omnilux Revive and Blue Combination' and the previously approved Omnilux Revive (K030426) and Omnilux Blue (K030883) devices and their respective predicates. Therefore, the Omnilux Revive and Blue Combination raises no new issues of safety or effectiveness.

The new intended use is detailed in Appendix 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2005

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

Re: K043329
Trade/Device Name: Omnilux Revive and Blue Combination
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 1, 2005
Received: February 7, 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

K043329

Device Name Omnilux Revive and Blue Combination

Indications for Use:

The Omnilux Revive and Blue Combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

...Restorative
...vices

K043329