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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.

JAN 16 2009

1. General Information

Submitter: Photo Therapeutics Inc
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Summary Preparation Date: 18th May 2007
Amended: 20th July 2007 (Contact Person corrected)

2. Names

Device Name: Omnilux Clear-U

Classification Name: Laser Instrument, Surgical Powered - General and Plastic Surgery - Class II, OLP

Although this device is not a laser and is intended for OTC use, the manufacturer thinks this is the closest applicable classification name.

3. Predicate Devices

Omnilux Revive (K030426), Omnilux blue (K030883), Omnilux revive/Omnilux blue combination (K043329).

4. Device Description

The Omnilux Clear-U is a source of high spectral purity It provides uniform or "hot-spot" free illumination The outputs are pre-tuned to a particular wavelength with a narrow spectral bandwidth The red output of the Omnilux Clear-U is 633 ± 6 nm, and the blue output is 415 ± 5 nm The Omnilux Clear-U device itself contains a selector switch (red/off/blue), the LED array assembly, and arrangements for air cooling A separate, universal, power supply converts mains AC power to the DC power required by the Omnilux Clear-U Treatment time is controlled by the operator

5. Indications for Use

The Omnilux Clear-U is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face The target patient population for the Omnilux Clear-U is the same as that for the predicate devices, however the Omnilux Clear-U is designed for home use

6. Performance Data

Photo Therapeutics Limited believes that no significant differences exist between the previously approved Omnilux revive (K030426), Omnilux blue (K030883), Omnilux revive/Omnilux blue combination (K043329) and the Omnilux Clear-U Therefore, the Omnilux Clear-U raises no new issues of safety or effectiveness

This belief is based upon

- An analysis of the overall performance characteristics for the device
- The results of a self-selection test (carried out on a sample representative population using the product labeling) which showed a minimum comprehension rate for the critical objectives of 93% at the 95% confidence level
- The results of a usability test (carried out on a sample representative population using the product labeling) which showed a minimum comprehension rate for the critical objectives of 88% at the 95% confidence level

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2009

Photo Therapeutics, Inc
% Ms Sue Darcy
CEO
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Carlsbad, California 92010

Re K081307
Trade/Device Name Omnilux Clear-U
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 OLP
Dated December 23, 2008
Received December 29, 2008

Dear Ms Darcy

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 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 (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

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

Enclosure

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Device Name Omnilux Clear-U

Indications for Use

The Omnilux Clear-U is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face

Prescription Use ____ AND/OR Over the Counter Use ✓
(Per 21 CFR 801 109)

(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 K081307