K072459

MAR - 3 2008

510(k) Summary of Safety and Effectiveness for the Photo Therapeutics Limited Omnilux New-U

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 Inc
2720 Loker Avenue West
Carlsbad
California
CA 92010

Contact Person:
Sue Darcy
Chief Executive Officer
Photo Therapeutics Inc
2720 Loker Avenue West
Carlsbad
California
CA 92010

Summary Preparation Date: 8th August 2007

2. Names

Device Name: Omnilux New-U

Classification Name: Laser Instrument, Surgical Powered - General and Plastic Surgery - Class II, 79-GEX

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 plus (K043317), Omnilux revive/Omnilux plus combination (K050216).

4. Device Description

The Omnilux New-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 New-U is 633 $\pm$ 6 nm, and the IR output is 830 $\pm$ 5 nm. The Omnilux New-U device itself contains a selector switch (red/off/IR), 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 New-U. Treatment time is controlled by the operator.

5. Indications for Use

The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum, specifically indicated to reduce periorbital wrinkles. The target patient population for the Omnilux New-U is the same as that for the predicate devices, however the Omnilux New-U is designed for home use.

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 previously approved Omnilux revive (K030426), Omnilux plus (K043317), Omnilux revive/Omnilux plus combination (K050216) and the Omnilux New-U. Therefore, the Omnilux New-U 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

Photo Therapeutics, Inc.
% Ms. Sue Darcy
Chief Executive Officer
2720 Loker Avenue West
Carlsbad, California 92010

MAR - 3 2008

Re: K072459
Trade/Device Name: Omnilux New-U
Regulatory Number: 21 CFR 878.4810
Regulatory Name: Light based over the counter wrinkle reduction
Regulatory Class: II
Product Code: OHS
Dated: January 22, 2008
Received: January 24, 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

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 (DGRND/GSDB)
D.O.
f/t:KSB:tlm:1-28-08

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Last Updated: Brandi Stuart – 7/9/07

Device Name Omnilux New-U

Indications for Use:

The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

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 k072459