K030426

JUL 17 2003

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

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:	Maureen O'Connell 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-207-1246
Summary Preparation Date:	May 6, 2003

2. Names

Device Name:	Omnilux Revive
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: 79

3. Predicate Devices

The Omnilux Revive is substantially equivalent to a combination of the following devices: the IPL Quantum SR manufactured by Lumenis, Inc. and subject of K020839; the Aurora SR manufactured by Syneron Medical Ltd. and subject of K022266; and the EsteLux manufactured by Palomar Medical Technologies, Inc. and subject of K020453.

4. Device Description

The Omnilux Revive is an intense visible 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 633 $\pm$ 5 nm. The Omnilux Revive 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 is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.

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 Revive 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

JUL 17 2003

Photo Therapeutics Limited
c/o Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K030426
Trade/Device Name: Omnilux Revive
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: May 6, 2003
Received: May 8, 2003

Dear Ms. O'Connell:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K030426

Device Name Revive

Indications for Use:

The Revive is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.

(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)

Miriam C. Provost (~~Optional~~ Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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