JAN - 4 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____. K082586

1. General Information

Submitter:	LIGHTWAVE Technologies LLC 2222 W. Parkside Lane Suite 111 Phoenix, AZ 85027 United States
Contact Person:	Mike Poling President LIGHTWAVE Technologies LLC 2222 W. Parkside Lane Suite 111 Phoenix, AZ 85027 United States
Summary Preparation Date:	August 21, 2008

2. Names

Device Name:	LIGHTWAVE Professional Deluxe
Common Name:	laser instrument, surgical powered, infrared lamp
Regulation:	878.4810, 890.5500
Product Code:	GEX, ILY

3. Predicate Devices

Photo Therapeutics Ltd. K030883, Omnilux Revive (K030426), Omnilux Plus (K043317), Omnilux Revive and Plus Combination (K050216).

4. Device Description

The LIGHTWAVE™ Professional Deluxe System uses high-end Light Emitting Diodes (LED's) to distribute the specific wavelengths of light it uses. This technology is commonly referred to as Photobiostimulation, Light Emitting Diode Therapy (LEDT), LLLT, or LED's. The application of LED's to tissue is non-invasive.

These devices are solid state and hand free mounted for placement directly over the skin where the treatment is to occur.

The LIGHTWAVE Professional Deluxe LED system is a combination of two sources of high chromatic accuracy. They provide uniform even coverage exposure area. The output wavelengths of LIGHTWAVE Professional Deluxe Range from 630 nm (visible red) to 830nm (near infrared). The LIGHTWAVE Professional Deluxe base unit contains the power supplies and the control unit. The LED panel can be configured to contain one (1), two (2) or three (3) row(s) of LED (600, 1200 or 1800 LEDs respectively) based on system configuration. The LED panel is 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 LIGHTWAVE Deluxe Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.

The LIGHTWAVE Deluxe Red and Blue light 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.

THE LIGHTWAVE Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

THE LIGHTWAVE Deluxe Red and Blue light combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

THE LIGHTWAVE Deluxe Infrared Light 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, LIGHTWAVE Technology believes that no significant differences

exist between the LIGHTWAVE Professional Deluxe and the predicate devices listed above made by Photo Therapeutics.

7. Comparison to Predicate Devices:

The intended use and major performance parameters (energy transmission levels and wavelength) of the LIGHTWAVE Professional Deluxe are similar or equivalent to the same characteristics of the Photo Therapeutics Omnilux devices.

8. Testing

Formal clinical trials were not deemed necessary as the device is using the same technology and intended use as the predicate devices.

Testing information demonstrating safety and effectiveness of the LIGHTWAVE Professional Deluxe in the intended environment of use is supported by testing that was conducted in accordance with the following standards: IEC 60601-1 and IEC 60601-1-2:2001.

10. Conclusions

Based upon an analysis of the overall characteristics for the device in comparison to the predicates, LIGHTWAVE Technologies concludes that the LIGHTWAVE Professional Deluxe is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 4 2010

LIGHTWAVE Technologies L.L.C.
% MDI Consultant, Inc.
Ms. Maria F. Griffin
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K082586
Trade/Device Name: Lightwave Professional Deluxe
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 20, 2009
Received: November 23, 2009

Dear Ms. Griffin:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit # 3

Indications for Use

510(k) Number (if known): K082586

Device Name: Lightwave Professional Deluxe

Indications For Use:

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Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR **Over-The Counter Use_____** (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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K082586