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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.

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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

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

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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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Exhibit # 3

Indications for Use

510(k) Number (if known): K082586

Device Name: **Lightwave Professional Deluxe**

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.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K082586 /A001

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2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
1-866-999-6954 (TF)
(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

RETURN RECEIPT REQUESTED

FDA CDRH DMC

DEC 10 2009

Received

K-32

December 8, 2009

Office of Device Evaluation
U. S. Food and Drug Administration
Center for Devices & Radiological Health
Document Mail Center – WO66 Room G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference: Additional Information Response for 510(k): K082586

Dear Sir/Madam:

Pursuant to the above-captioned 510(k) submissions, the following information is being submitted to Document Mail Center per the request of reviewer, Richard P. Weiblinger, FDA requesting additional information.

We have prepared our responses in the order of the questions presented to us by the letter as follows:

Question 1:

Response 1:

Question 2:

Response 2:

We trust that the aforementioned responses will be satisfactory.

If you have any questions, or require additional information, please feel free to call me at 1-866-999-6954 or 602-738-4226 or email me at mikep@mylightwave.com.

Sincerely,

Michael Poling
President
Lightwave Technologies, LLC
Attachments

A complete list of Attachments is annexed hereto.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Question 1 (via telephone with Rick Weiblinger and Richard Felton):

The reviewers asked us to update the comparison tables and total dosage for the periorbital wrinkle and acne treatments. The reviews also requested that we expand the directions for use to include information about dosage and an additional warning regarding caution needed when using the higher setting(s).

Response 1

(b) (4)

[redacted]

Question 2 (via telephone with Rick Weiblinger and Richard Felton):
The reviewers asked us to update the inconsistent labeling on the IFU form, Summary sec. 3 and sec. 5 and User Manual. Review noted that User Manual labeling for IFU is correct and should be consistent throughout.

Response 2

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIST OF ATTACHMENTS

Attachment 1	Updated User Manual
Attachment 2	510(k) Summary
Attachment 3 & 4	Updated Comparison Charts
Attachment 5	Indications For Use (IFU) Form

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NOTICE: READ BEFORE OPERATING

The information supplied throughout this document should be used only as a guideline and does not constitute or replace medical advice. LIGHTWAVE™ Technologies is registered with the FDA.

- This manual must be kept for quick reference on use, cautions, maintenance and repair.
- Read this manual in its entirety before using the LIGHTWAVE™ system.
- Improper use of the LIGHTWAVE™ system can void the warranty. Please familiarize yourself with the limitations of the warranty and proper handling and storage of the system.
- The goggles included with the LIGHTWAVE™ unit are to be used at all times while operating any setting on the system. Due to the specific protection of the safety eye wear; they should never be used as protection with any other light or laser systems. Company issued replacement plastic goggles, stainless steel framed safety glasses, and disposable LED shields have all been shown to be effective. These varieties of eye protection are available for purchase through LIGHTWAVE™ Technologies.
- Should the panel ever come in direct contact with the skin for any reason, LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol swab to avoid cross contamination. NEVER clean the panel when the unit is powered "ON."
- WARNING: Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the LIGHTWAVE Professional Deluxe by children or incapacitated persons may be dangerous.

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No part of this instruction manual may be used to make derivative works based upon the original. No part of this information may be passed on, written down or used for commercial or private reproduction or any other purpose not specifically mentioned unless and until LIGHTWAVE™ Technologies LLC gives its written permission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Getting Started

LIGHTWAVE™ systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

Introduction

Thank you for choosing LIGHTWAVE™. This operating manual contains information on our LIGHTWAVE™ Professional light therapy system.

Below you will find a general overview of the LIGHTWAVE™ system as well as detailed sections throughout this guide providing you comprehensive knowledge of our systems' operation, and guidance on how to maintain it for years to come.

Please read the safety sections in their entirety before operating the system.

Again, we appreciate your confidence in LIGHTWAVE™ Technologies. Our customer care team welcomes any and all feedback with regard to our equipment. We can be reached by dialing toll-free at 866-999-6954.

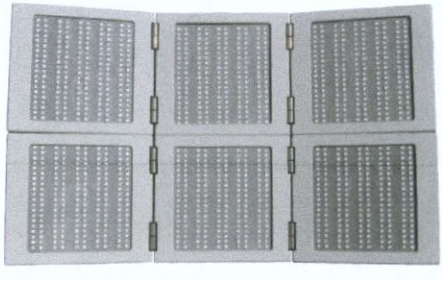
System Overview

All LIGHTWAVE™ systems include a main unit and one accessory item.

Main Unit:

LIGHTWAVE's main unit features one touch button operation, a large LCD screen display, 3 accessory sockets, power supplies, operational software, and a locking on/off key switch.

Panels:



LIGHTWAVE's basic accessory item is the LED arm panel. It utilizes Red (630 nm), Infrared (880 nm) and Blue (420 nm) wavelengths. However, multiple wavelengths should ever be used simultaneously, use only one wavelength at a time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them. Each panel contains movable sections with independent hinges allowing it to adjust and form around the area being treated. This allows the panel to maintain a uniform distance from the treatment area which enables an even amount of light to be distributed. Please refer to *Positioning the Panel* for specific details on placing the panel over the treatment area.

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System Specs and Details

Output Intensity	Red 112 mW/cm2 Infrared 57mW/cm2 Blue 45mW/cm2
Output Wavelength	Red 630nm Infrared 880nm Blue 420 nm
Bandwidth	Red 25nm +/- 5nm Infrared 25nm +/- 5nm Blue 25nm +/-- 5nm
Light Source	SL SMT LED
Pulse	CW & Variable
Energy	1-168 joules
Coverage Area	Up to 1668 cm2
Electrical Supply	AC 110v or 220v
Weight	50lbs
Size	58 in (h) x 24 in (w)
Color	White, Grey and Black

Storage

The main unit is shipped inside a pink anti-static bag. This bag must be retained for future shipping needs should they arise. Failure to do so will result in additional material and handling charges.

Thoroughly clean the panel after each use and prior to storing. Please see *User Maintenance* for specific cleaning instructions.

When not in use, store the main unit and panel in a dust free environment to prolong the life of your system.

User Maintenance

Power off and unplug the LIGHTWAVE™ main unit prior to cleaning the system.

Any time the panel comes in direct contact with the patient's skin or that of the operator; LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol pad to avoid cross contamination. This is for your protection and the protection of your clients. Do not spray the system or accessories directly with an anti-bacterial solution but rather dampen a cloth with the solution and wipe down the panel and main unit. Never clean the panel when the unit is powered "ON."

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Safety Warnings

Listed below are general safety instructions that apply to the operation of LIGHTWAVE™ equipment. This list includes many, but not all, of the safety instructions. Also refer to the safety guidelines and warnings shown in the rest of this manual and on the equipment.

Read this manual and all safety labels in their entirety before operating the equipment.

Do not operate the LIGHTWAVE™ around water as this can increase the risk for electrical shock. If liquid is spilled on the equipment, unplug the unit and call LIGHTWAVE™ immediately.

Do not operate the LIGHTWAVE's™ equipment around flammable liquids or gases. Doing so increases the danger of possible fire or explosion.

Do not restrict airflow to the panel or main unit. See *Positioning the Panel* for specific details on placing the panel over the treatment area. Make sure all air flow openings on the main unit are unobstructed and have proper ventilation.

If any wiring becomes exposed on the LED panel cable or power cord, do not operate equipment. Doing so can increase the risk for possible electrical shock

Use only the power source provided with the LIGHTWAVE equipment. Static electricity can cause harm to your system.

LIGHTWAVE's™ equipment should have its own dedicated wall socket or power strip. Do not power the equipment with a shared power strip.

Do not place foreign objects on or near the LIGHTWAVE™ equipment.

Never attempt to open the main unit or panel. Doing so puts the operator at risk for electrical shock. In addition, it voids all warranties and will cause permanent damage to your system.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, laying on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin.

Specific Safety Warnings: Eyes

The LIGHTWAVE™ equipment has been classified as a CLASS 2 device. The device is only capable of emitting low powered light at certain wavelengths making it incapable of causing eye injury within the normal aversion response to intense light.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The output of light produced during a treatment is greater than the recommended Maximum Permissible Exposure (MPE's) in the Blue and Infrared spectrum. It is absolutely imperative that the following guidelines are adhered to when operating the LIGHTWAVE™ equipment for the treatment of acne and for the temporary relief of minor muscle and joint pain.

The goggles provided with the LIGHTWAVE™ equipment are to be worn by the patient at all times when treatments are performed on or around the face and neck area. Goggles must be properly fitted over the retina and thoroughly disinfected with an anti-bacterial solution between treatments to avoid cross contamination.

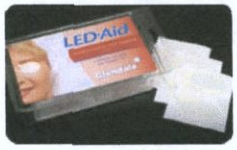
When treating your patient's face and neck area with blue or infrared light, it is essential to protect your client's eyes. In order to ensure proper protection and completely safeguard your client, apply the provided disposable LED eye aids under the standard LIGHTWAVE™ goggles. Optional metal block-out goggles are available for those clients who find the use of the disposable LED eye aids uncomfortable.

When treating other areas of the body (face and neck excluded), LIGHTWAVE™ recommends that the patient close their eyes for the entire duration of the treatment.

The operator does not directly view the light source for an extended period of time and therefore has a higher Maximum Permissible Exposure time. Due to the increased MPE time, the operator is not required to use protective eyewear. However, in order to properly protect the operator and limit their exposure time, IPL or Laser goggles are recommended.

Standard LIGHTWAVE supplied goggles

Optional LIGHTWAVE metal block-out goggles



LIGHTWAVE supplied disposable LED Aids

Contraindications

The safety of light therapy has been tested and no significant adverse reactions have been noted. However, using light therapy when treating patients with specific high-risk conditions has not been thoroughly established. Therefore, as a precaution LIGHTWAVE recommends not treating children or patients with the following conditions:

Acute or Cutaneous Porphyria, Lupus Erythematosus, Thyroid Problems, Photophobia Exogenous Eczema, Epilepsy & Seizures, Hypomelanism (albinism), Skin Cancer, Migraines Eye disease/retinal abnormalities, Diabetes, Pregnancy.

Specific to Acne Patients:
In rare cases cystic acne can increase rather than improve. Cystic acne patients should discontinue the light therapy treatment if they react unfavorably to the treatment. For any acne patient, if their condition worsens instead of improves, the solution is less light not more.

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The following medications have been known to cause light sensitivity. If possible, medications listed below must be suspended for a minimum of one week before undergoing light therapy. If it is not possible to discontinue the use of a medication then your client must consult with their doctor before undergoing light therapy while continuing on the medication. It is further imperative that your client check with his/her doctor before discontinuing any prescribed medications.

Anti-Arrhythmic:	**Amiodarone** (Pacerone® Cordarone® Aratac®)
	Chlorpromazine (Thorazine®, Chloramead®, Chlordryprom®, Chlor® Promanyl®, Largactil®, Promapar®, Promosol®, Terpium®, Sonazine®)
Acne:	**Oral Isotretinoin** (Accutane®, Accure®, Aknenormin®, Amnesteem®, Ciscutan®, Claravis®, Isohexal®, Isotroin®, Oratane®, Sotret®, Roaccutane®)
	Topical Isotretinoin (Isotrex®, Isotrexin®)
Anti-Psychotic:	**Haloperidol** (Haldol®)
	Trifluoperazine (Stelazine®, Clnazine®, Novoflurazine®, Pentazine®, Solazine®, Terfluzine®, Triflurin®, Tripazine®)
Anti-Fungal:	**Griseofulvin** (Grifulvin®)
Antibiotics:	**Tetracycline** (Helidac®, Terra-Cortril®, Terramycin®, Sumycin®, Actisite®, Bristacycline®, Actisite®, Tetrex®, Doxycycline®, Ciprofloxacin®)
	Norfloxacin (Noroxin®, Quinabic®, Janacin®)
	Ofloxacin (floxin®, Oxaldin®, Tarivid®)
	Nalidixic acid (NegGam®, Wintomylon®)
	Ciprofloxacin (Cipro®, Ciproxin®, Ciprobay®)
	Minocycline (Minomycin®, Minocin®, Arestin®, Akamin®, Aknemin®, Solodyn®, Dynacin®, Sebomin®)
	Oxytetracycline
	Demeclocycline
	Lymecycline
Cancer:	**Methotrexate** (MTX®, Aminopterin®, Ledertrexate®)
Arthritis:	**Auranofin** (Ridaura®)-***If a patient is taking this medication; they are not a candidate for light therapy.***

The above drugs are currently the most common medications associated with photosensitivity and are by no means a complete list of all photosensitive medications. Herbs and over the counter medications such as psoralen and St. John's Wort can also cause sensitivity to light so it is important to stress to your client that they disclose any and all medications or herbs they are currently taking.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIGHTWAVE Deluxe System

Intended 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating Instructions

Deluxe System Contents

1 – Control Unit
2 – Control Unit Keys
1 – 6ft Power Cord
1 - Stand with Casters and 2 Trays
1 - Arm with pole bracket
2 - 3 pc LED arm panels
1 - LED panel main cable
1- Power Surge Protector
1- Protective Eye Wear
1- User Manual and Protocol booklet

To Get Started

Image 1 - All LCU's come equipped with a 4-amp fuse to protect the unit from power surges. Always disconnect the power before accessing fuse.

Place the LIGHTWAVE™ Main Control Unit, (MCU) on a stable, flat surface or on the LIGHTWAVE™ stand. To turn on the LIGHTWAVE™ unit, connect the female end of the electrical power cord to the back of the unit. Plug the male connector into the **surge protector,** which needs to be connected to a standard 110v electrical outlet. Next, flip the On/Off switch to the **on (-)** position on the back of the MCU (See picture on the left).

Connecting LED Pads or Arm Assembly

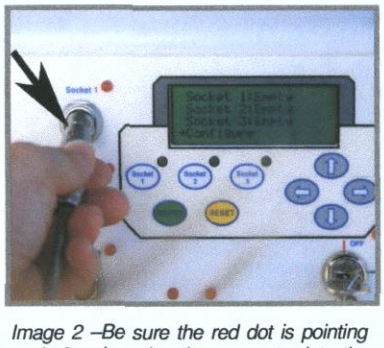

Image 2 –Be sure the red dot is pointing up before inserting the connector into the socket port.

In order to connect the LED Panel assembly, the operator must first identify the RED dot on the collar of the connector tip. The red dot aligns pointing directly upwards when connecting the panel to the main control unit. After connecting the panel cord to the main unit, the cord needs to be connected to the arm panel. When connecting the arm cord to the arm panel, the red dot aligns pointing directly downwards instead of upwards as it did when you connected the cord to the base. After connecting the LED panel, the operator can turn ON the power switch if it has not already been done, which is located on the back of the MCU (LED panel may be plugged in with the power on or off). Upon starting, the unit will move through a number of initial screens that identify the machine's version of software and the model number. Then the control screen will indicate the present status of each socket.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00047

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Setting the Preset Programs

When the panel is connected to the MCU, the green indicator nearest to the corresponding socket button is illuminated indicating a good connection between the panel and the MCU (if you have correctly connected the panel and the green light is not lit, please consult Tech Support).

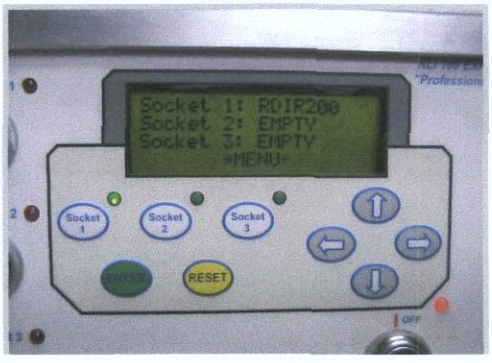
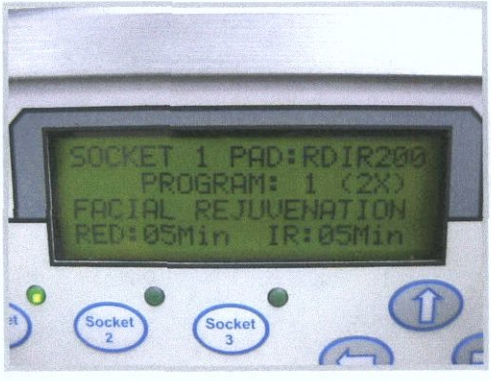


*Image 3-The **Main Control Display** pictured to the left shows that a main panel is plugged into socket one and the green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button that corresponds to the panel that has just been connected will bring up the **Socket Status Display** for that socket. The socket status display should appear as below.

*Image 4-The **Socket Status Display** pictured to the right shows that a main panel is plugged into socket one. The green light next to the socket one button indicates that socket one is ready.*



Pressing the socket button again brings a blinking cursor to the program number. Using the up and down arrow keys allows the user to change from one program to the next. When the desired program is displayed, press enter, the blinking cursor will go away and the LIGHTWAVE™ unit is now ready to begin a treatment session. Pressing enter for a second time will start the treatment session. Please see *Performing Treatments* before initiating a treatment session.

Using the Machine "LOCK" Option

As an added safety feature, the operator can restrict the use of the machine from other users. By simply turning the key to the "OFF" position, the display will read "LOCKED" and no operations can be performed, completely disabling the LIGHTWAVE™ unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Using the "MENU"

The MENU can only be accessed from the **Main Control Display**. By pressing the RESET button, the user is sent to the Main Control Display screen. With the arrows blinking on either side of the word "MENU", press the ENTER button and the words similar to below will be shown. (Each one of the MENU options can be accessed by moving the blinking arrows with the up and down arrow keys.)

SET TIME AND DAY: Simply use the up and down arrow keys, along with ENTER to set the time and date.

ADD TREATMENTS: This function is for the units that are contracted on a pay per treatment program or other contract. Call Tech Support when using this menu.

RETURN: Returns the display to the Main Control Display.

Performing Treatments

Positioning the Panel

The proper placement of the panel is extremely important. If the panel is not correctly positioned over the treatment area, the dosage of light delivered can vary and affect the treatment outcome.

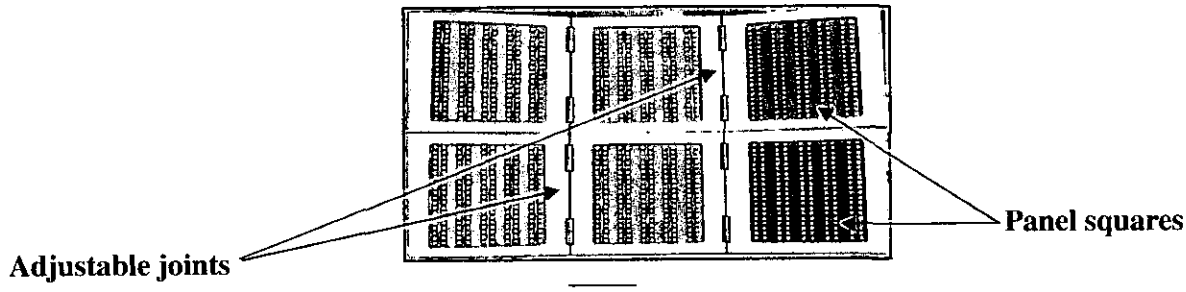
CAUTION: Never place the panel directly on open wounds, sunburns, or sensitive tissue. Restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin. If the panel is placed directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

NOTE: Never activate two separate wavelengths at the same time, only one wavelength should be used at one time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them.

Please follow these simple steps when positioning the panel:

1. Select the desired treatment area; keeping in mind the treatment area should not exceed the size of the panel. If the desired treatment area exceeds the panel size, additional treatments will need to be performed on the treatment area that extends beyond the panel boundaries.

2. The LED panel is designed with six adjustable joints and squares so that the panel will lay flat when treating surfaces such as the back or contour around a selected target area such as the face. Always adjust the panel at the joint.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00049

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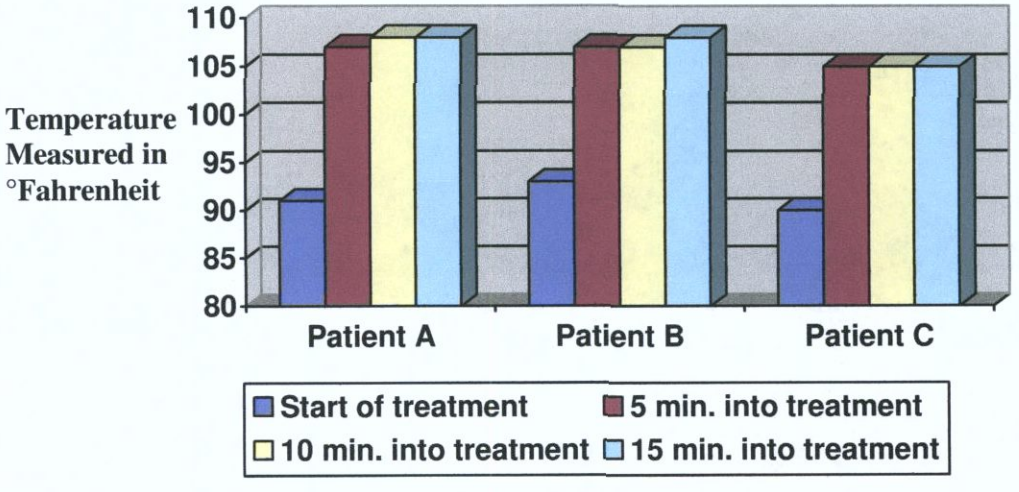
3. When positioning the panel for a cosmetic treatment, evenly place the individual LED squares 1 inch from the target treatment area. When treating an uneven surface such as the face, the furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the panel at all times should remain within ½-1 inch from the surface of the target area. If the panel extends beyond the area of concern, the additional area will be exposed to light therapy. The further away the area is from the panel, the less photon energy the area will absorb. If you do not want to expose an area of skin to light, the excess skin can be covered with a thick cloth.

4. When positioning the panel for a treatment addressing a concern dealing with pain and discomfort within the body, the panel needs to increase the skin temperature to 104°F -113°F and maintain the elevated temperature throughout the duration of the treatment. In order to do so, you must evenly place the individual LED squares ½ inch from the target treatment area. When treating an uneven surface, the furthest extended point should be no more than ½ inch and no closer than ¼ inch from the LED panel. In order to ensure proper dose and temperature, the panel at all times should remain within ¼-½ inch from the surface of the target area.

AVERAGE SKIN TEMPERATURE READINGS FOR IR SETTING



As noted from the chart above, three patients' temperature readings were taken over a 15 minute treatment span. Based on the performance data, the IR setting on the panel is capable of raising and maintaining an elevated area temperature ranging from 104°F-109°F if the panel is correctly placed over the area of concern. Proper placement of the panel is essential in treating inflammation of the joints and muscle discomfort. If the panel is not within ½ of the target area, it is not capable of maintaining an elevated temperature throughout the treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Starting a Treatment

Once you have correctly set-up your system and properly positioned the LED panel, you are ready to start a treatment session. Before starting a treatment session, please read the *Protocol Usage Manual* so that you are familiar with the various treatment options.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Please read *Safety Warnings (pg. 5)* before starting a treatment.

Please follow the steps below to start a treatment:

1. Select the proper treatment setting corresponding to the desired treatment. Make sure the monitor exhibits the Socket Status Display screen (See image 4, pg. 10) by pressing the corresponding socket button to the matching treatment socket. Press the ENTER button. The screen will display a default setting for each program and is pre-set with the standard dose (See table 1, pg. 13.) To adjust the dose, use the left and right arrows to move the cursor to the number below the word DURATION (MIN). Once the number is highlighted, use the up and down arrows to decrease or increase the number which will adjust the time and dose according to the chart listed below.

2. Once the proper MIN have been selected press the ENTER button to activate the program. The Red indicator light should illuminate next to the socket that corresponds to the treatment socket that was just started. As long as the Red indicator is lit, this socket is active. Do not remove the arm panel until the treatment is complete. If a patient feels uncomfortable in any way proceed with the following - **Note: To Stop a Treatment, Press the "RESET" button in the Socket Status Display Screen. The custom setting will be saved until the main unit has been turned off. Custom Programs are not available on Pads.**

Dosage According to Panel Treatment Times				
Duration (min.)	**Infrared 880nm**	**Red 630nm**	**Blue 420nm**	
	57 mW/cm2	**112 mW/cm2**	**45mW/cm2**	
1	3.46 J/cm2	6.73 J/cm2	2.70 J/cm2	
5	17.28 J/cm2	33.66 J/cm2	13.50 J/cm2	
10	34.56 J/cm2	67.31 J/cm2	27.00 J/cm2	
15	51.84 J/cm2	100.97 J/cm2	40.50 J/cm2	
20	**69.12 J/cm2**	**134.63 J/cm2**	**54.00 J/cm2**	**Standard Dose**
25	86.40 J/cm2	168.29 J/cm2	67.50 J/cm2	* See warning below.

*Warning- There is no clinical data to substantiate the higher dose setting(s) at this time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Applications

TREATING MILD TO MODERATE ACNE

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. However, only one wavelength should be used at a time. Never use blue and red simultaneously as this can reduce the treatment efficacy. The red light is capable of delivering a standard dose of 134.63 Joules/cm² in 20 minutes. The blue light is capable of delivering a standard dose of 54 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to Eye Safety Concerns for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to Placement of Panel (pg. 11) for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system; never using blue and red simultaneously as this can reduce the treatment efficacy. Please refer to Starting a Treatment (pg. 13). An initial eight treatment series starting with blue is recommended for this protocol over a 4 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week eight, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for MILD TO MODERATE ACNE (2 treatments per week with a minimum of 48 hours between treatment sessions. Never use red and blue together as this reduces efficacy.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take several bench mark photos.	✓			✓				✓
2	Cleanse skin with an anti-bacterial wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Blue Light session.	✓		✓		✓		✓	
4	Start 20 minute Red Light session.		✓		✓		✓		✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TREATING MODERATE INFLAMMATORY ACNE

THE LIGHTWAVE Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The blue light is capable of delivering a standard dose of 54 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles *in place simultaneously*, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial eight treatment series of blue is recommended for this protocol over a 4 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week eight, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for MODERATE INFLAMMATORY ACNE (2 treatments per week with a minimum of 48 hours between treatment sessions.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take several bench mark photos.	✓			✓				✓
2	Cleanse skin with an anti-bacterial wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Blue Light session.	✓	✓	✓	✓	✓	✓	✓	✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TREATING PERIORBITAL WRINKLES

THE LIGHTWAVE Deluxe Red and Infrared light combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The red light is capable of delivering a standard dose of 134.63 Joules/cm² in 20 minutes. The infrared light is capable of delivering a standard dose of 69.12 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an exfoliating wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. A micro-exfoliating scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial seven treatment series is recommended for this protocol over a 5 week period. The client should receive an infrared LED light therapy treatment two times a week for the first week with at least 48 hours between treatment sessions. During week two, the client should receive two LED red light therapy treatments with at least 48 hours between treatment sessions. During weeks three, four, and five, the client should receive one infrared light therapy treatment each week. Before, during, and after photos should be taken at a minimum on week one, week four and week seven, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 7 LIGHTWAVE TREATMENT SESSIONS for PERIORBITAL WRINKLES **(1-2 treatments per week with a minimum of 48 hours between treatment sessions. Never use red and infrared together as this reduces efficacy.)**		**Session 1 (week 1)**	**Session 2 (week 1)**	**Session 3 (week 2)**	**Session 4 (week 2)**	**Session 5 (week 3)**	**Session 6 (week 4)**	**Session 7 (week 5)**
1	**Take several bench mark photos.**	✓			✓			✓
2	**Cleanse skin with an exfoliating wash.**	✓	✓	✓	✓	✓	✓	✓
3	**Start 20 minute Infrared Light session.**	✓	✓			✓	✓	✓
4	**Start 20 minute Red Light session.**			✓	✓			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TREATING MINOR MUSCLE AND JOINT PAIN

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. The Infrared light is capable of delivering a standard dose of 69.12 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Caution should be taken not to place the panel directly on an open exposed cut or wound. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

When treating discomfort near the face and eye area, shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *placement of Panel (pg. 11)* for complete information on proper protection. If the area of concern is not near the face or eye area, the client still needs to close their eyes throughout the treatment session.

Step Three: Treatment Instructions

An initial minimum treatment series of four is recommended for this protocol over a two week period. The client should receive LED light therapy treatments two times a week with at least 24 hours between treatment sessions until the discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort the client actually experiences. If necessary, a client may continue treatment twice a week for up to a total of five weeks before discontinuing treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting

LIGHTWAVE's Basic Troubleshooting Guide

Problem	Possible Source	Mandatory Action
No Power	Power cable unplugged	Connect power cable to a working outlet
No Power	Surge Protector not on	Turn on surge protector
No Power	Power switch is set to "OFF" position	Turn switch to "ON" position
Display shows "LOCKED"	Key is set to "ON" position	Turn key to "OFF" position
System Shows "Panel READ ERROR"	Static build up	Unplug all devices from system and turn power off. Wait 2 minutes and turn on system without ay devices plugged in. Once system is completely on plug in devices one at a time.
"This device requires socket 1"	Device that requires socket 1 was plugged into socket 2 or 3.	Unplug device from socket 2 or 3 and plug into socket 1.
Program not turning on	Device not plugged into system correctly	Ensure that the device is plugged into the system and it is registered on the "Main Menu" screen.
Displays "Call Tech Support"		Call Tech support at 1-866-999-6954
Main Unit keeps asking for a confirmation #		Call Tech support for code

If the above actions do not rectify the problem or if an error occurs not listed on in the table, please call our help desk at 1-866-999-6954.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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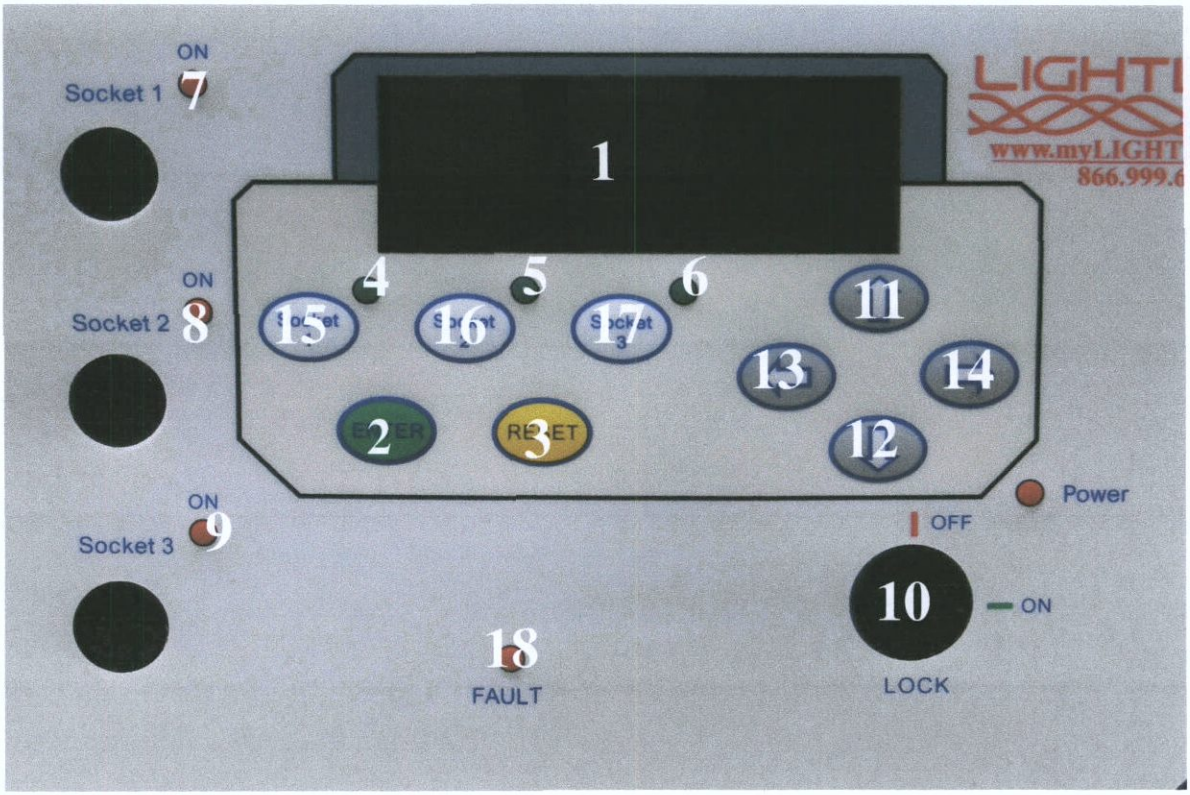
Control Unit Membrane Index

MEMBRANE CONTROL SCREEN



1. LCD Display
2. Enter Button
3. Reset Button
4. Socket 1 Display Status Button
5. Socket 2 Display Status Button
6. Socket 3 Display Status Button
7. Socket 1 and Socket 1 Active Indicator
8. Socket 2 and Socket 2 Active Indicator
9. Socket 3 and Socket 3 Active Indicator
10. LOCK
11. Up Arrow
12. Down Arrow
13. Left Arrow
14. Right Arrow
15. Socket 1 Button
16. Socket 2 Button
17. Socket 3 Button
18. Fault Indicator

Please call us toll free at (866) 999 - 6954 Monday – Friday MST from 8:00 – 5:00 so we may address any questions or concerns you have with regard to this manual, protocols, usage, etc.

Once again, thank you for choosing LIGHTWAVE™.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00057

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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:_____.

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.

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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

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00060

	LED Predicates Comparison Chart & Specifications Part 1 Red & IR						
Company	**LIGHTWAVE Technologies LLC**		**Photo Therapeutics, Ltd.**		**Photo Therapeutics, Ltd.**		**SE or Different**
Device Name	**LIGHTWAVE Professional DELUXE**		**Omnilux Revive**	**Omnilux Plus**	**NEW-U**		
Decription	**LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions**		**LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions**		**LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions**		**SE**
K Number	to be assigned	to be assigned	K050216		K072459		N/A
Regulation Number	878.4810	890.5500	878.4810	890.5500	878.4810		N/A
Product Code	GEX	GEX	GEX	GEX	GEX		SE
Light Source	LED (noncoherent) Multi diode		LED (noncoherent) Multi diode		LED (noncoherent) Multi diode		SE
Spectrum (wavelength)	Red: 630 nm	Infrared: 880 nm	Red: 633 nm	Infrared: 830nm	Red: 633 nm	Infrared: 830nm	SE
Delivery	Treatment Head - LED Array		Treatment Head - LED Array		Hand Held - OTC		SE
Output Intensity	Red: 112mW/cm2	Infrared: 57mW/cm2	Red: 105mW/cm2	Infrared: 55mW/cm2			SE
Treatment Time	Up to 20 min		Up to 20 min		Up to 20 min		SE
Standard Dose	Red: 134.63 J/cm2	Infrared: 69.12 J/cm2	Red: 126 J/cm2	Infrared: 66 J/cm2			SE
Dose range (adjustable)	Red: 1-168.29 J/cm2	Infrared: 1-86.4 J/cm2	Red: 1-150 J/cm2	Infrared: 1-80 J/cm2	Per its 510k (K072459) substantially equivalent to K050216		SE
Bandwidth	Red: 25nm +/-5nm	Infrared 25nm +/-5nm	Red: 20 nm +/- 3 nm	Infrared: 30 nm +/- 5nm	Red: 20 nm +/- 3 nm	Infrared: 30 nm +/- 5nm	SE
Wave Form	CW & Variable		CW	CW	CW	CW	SE
Head/LED configuration	All built into one head. No changing of heads.		Change head to change wavelength. Not all built into one head.		All built into one head. No changing of heads.		SE with K072459 minor difference with K050216
Target Population	Individuals Suffering from indicated dermatological conditions		Individuals Suffering from indicated dermatological conditions		Individuals Suffering from indicated dermatological conditions		SE
Type of use	Prescription use		Prescription use		Prescription use		SE
Spot Size (Coverage Area)	Up to 1662 cm2		541.12 cm2	541.2 cm2			Different
Intended use	The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and infrared region of the spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles. As well as for topical heating for the intended purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain		The OmniLux Revive was cleared (K030426) for the use in dermatology for the treatment of superficial, benign vascular and pigmented lesions. The Omnilux Revive and Plus combination was cleared (K050216) for dermatological conditions, specifically indicated to treat periorbital wrinkles.	The Omnilux Plus was cleared (K043317) for topical heating for the intended purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain. The Omnilux Revive and Plus combination was cleared (K050216) for dermatological conditions, specifically indicated to treat periorbital wrinkles	The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum, specifically indicated to reduce periorbital wrinkles.		SE
System Type	Table top/mobile workstation		Table top		Hand Held		SE
Size	58 in (H) x 24 in (W)		14 in (H) x 7 in (W)		5 in (H) x 2.5 in (W)		Different
Electrical Supply	AC 110VAC 220VAC 50/60 Hz		AC 110VAC 220VAC 50/60 Hz		AC 90-250VAC 50/60 Hz to DC		SE
Weight	84 lbs.		26 lbs		2.9 oz		Different

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DJA x00061

LED Comparison Chart & Technical Specifications Part 2 - Red & Blue					
Company	**LIGHTWAVE Technologies LLC**		**Photo Therapeutics, Ltd.**		**SE or Different**
Device Name	**LIGHTWAVE Professional DELUXE**		**Omnilux Revive**	**Omnilux Blue**	
Description	**LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions**		**LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions**		
K Number	to be assigned	to be assigned	K030426	K030883	N/A
Regulation Number	878.4810	878.4810	878.4810	878.4810	N/A
Product Code	GEX	GEX	GEX	GEX	SE
Light Source	LED (noncoherent) Multi diode		LED (noncoherent) Multi diode		SE
Spectrum (wavelength)	Red: 630 nm	Blue: 420 nm	633 nm	415 nm	SE
Delivery	Treatment Head - LED Array		Treatment Head - LED Array		SE
Output Intensity	Red: 112mW/cm2	Blue: 45 mW/cm2	105mW/cm2	40mW/cm2	Different
Treatment Time	Up to 20 min		Up to 20 min		SE
Standard Dose	Red: 134.63 J/cm2	Blue: 54 J/cm2	126 J/cm2	48 J/cm2	Different
Dose range (adjustable)	Red: 1-168.29 J/cm2	Blue: 1-67.5 J/cm2	1-150 J/cm2	1-55 J/cm2	Different
Bandwidth	Red: 25nm +/-5nm	Blue 20nm +/-5nm	20 nm +/- 3 nm	22 nm +/- 3 nm	SE
Wave Form	CW & Variable		CW		SE
Head/LED configuration	All built into one head. No changing of heads.		Change head to change wavelength. Not all built into one head.		SE with K072459 minor difference with K050216
Target Population	Individuals Suffering from indicated dermatological conditions		Individuals Suffering from indicated dermatological conditions		SE
Type of use	Prescription use		Prescription use		SE
Spot Size (Coverage Area)	Up to 1662 cm2		541.12 cm2		Different
Intended use	The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris and the treatment of superficial, benign vascular and pigmented lesions.		The OmniLux Revive was cleared (K030426) for the use in dermatology for the treatment of superficial, benign vascular and pigmented lesions. The Omnilux Revive and Blue combination was cleared (K043329) for dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	The Omnilux Blue was cleared (K030883) to treat dematological conditions specifically aimed at treating mild to moderate inflammatory acne vulgaris.The Omnilux Revive and Blue combination was cleared (K043329) for dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	SE
System Type	Table top/mobile workstation		Table top		SE
Size	58 in (H) x 24 in (W)		14 in (H) x 7 in (W)		Different
Electrical Supply	AC 110VAC 220VAC 50/60 Hz		AC 110VAC 220VAC 50/60 Hz		SE
Weight	84 lbs.		26 lbs		Different

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DJA x00062

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Exhibit # 3

Indications for Use

510(k) Number (if known): _____

Device Name: Lightwave Professional Deluxe

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.

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00001

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00002

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00003

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Exhibit # 3

Indications for Use

510(k) Number (if known): K082586

Device Name: Lightwave Professional Deluxe

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.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-9748

DJA K00090

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

July 02, 2009

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

510k Number: K082586
Product: LIGHTWAVE PROFESSIONAL DELUXE

Extended Until: 09/24/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00091

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

mdi

mdi Consultants, Inc.

Main Office: 55 Northern Blvd.
Suite 200
Great Neck, NY 11021
PH (516) 482-9001
FAX (516) 482-0186
email: mdi@mdiconsultants.com
website: www.mdiconsultants.com

RETURN RECEIPT REQUESTED

FDA CDRH DMC

JUL 02 2009

Received

June 30, 2009

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Request for 510(k) Extension
510(K) #K082586
Name of Device: Lightwave Professional Deluxe

Dear Sir:

Please grant us a 90 day extension on the above referenced 510(k).

If you have any questions, please contact me.

Thank you.

Sincerely,

mdi CONSULTANTS, INC.

Maria Griffin

Maria F. Griffin
Official Correspondent for
Lightwave Technologies, LLC

MFG/lo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00092

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 29, 2009

510k Number: K082586
Product: LIGHTWAVE PROFESSIONAL DELUXE

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2019-5756; Released by CDRH on 08-30-18

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00127

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 01, 2009

510k Number: K082586
Product: LIGHTWAVE PROFESSIONAL DELUXE

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00128

Records processed under FOIA Request 2007-5381, Release 1 of 1

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00239

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 31, 2008

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

510k Number: K082586
Product: LIGHTWAVE PROFESSIONAL DELUXE

Extended Until: 03/06/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00240

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

mdi

mdi Consultants, Inc.

Main Office: 55 Northern Blvd.
Suite 200
Great Neck, NY 11021
PH (516) 482-9001
FAX (516) 482-0186
email: mdi@mdiconsultants.com
website: www.mdiconsultants.com

RETURN RECEIPT REQUESTED

Received
DEC 30 2008
FDA CDRH DMC

December 29, 2008

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Request for 510(k) Extension
510(K) #K082586
Name of Device: Lightwave Professional Deluxe

Dear Sir:

Please grant us a 60 day extension on the above referenced 510(k).

If you have any questions, please contact me.

Thank you.

Sincerely,

mdi CONSULTANTS, INC.

Maria F. Griffin
Official Correspondent for
Lightwave Technologies, LLC

MFG/lo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00241

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

October 27, 2008

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

510k Number: K082586
Product: LIGHTWAVE PROFESSIONAL DELUXE

Extended Until: 01/07/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00242

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

mdi

mdi Consultants, Inc.

Main Office: 55 Northern Blvd.
Suite 200
Great Neck, NY 11021
PH (516) 482-9001
FAX (516) 482-0186
email: mdi@mdiconsultants.com
website: www.mdiconsultants.com

RETURN RECEIPT REQUESTED

October 23, 2008

FDA CDRH DMC

OCT 24 2008

Received

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Request for 510(k) Extension
510(K) #K082586
Name of Device: Lightwave Professional Deluxe

Dear Sir:

Please grant us a 60 day extension on the above referenced 510(k).

If you have any questions, please contact me.

Thank you.

Sincerely,

mdi CONSULTANTS, INC.

Maria Griffin/lo

Maria F. Griffin
Official Correspondent for
Lightwave Technologies, LLC

MFG/lo

E27

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00243

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

October 10, 2008

510k Number: K082586
Product: LIGHTWAVE PROFESSIONAL DELUXE

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00244

Records Released Under FOIA Request 2007-5561 Released by CDRH on 08-30-18

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00262

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

September 08, 2008

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD
SUITE 200
GREAT NECK, NY 11021
ATTN: MARIA F. GRIFFIN

510(k) Number: K082586
Received: 08-SEP-2008
Product: LIGHTWAVE
PROFESSIONAL DELUXE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federa Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited abov Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you whe the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medica device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, th Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regardin fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) nee to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new sectio 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/ FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issu

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00263

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Foo and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review:
1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process.
2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditiona or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/" If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Heal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18

K082586

DJA x00264

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

LIGHT WAVE TECHNOLOGIES
55 Northern Blvd., Suite 200
Great Neck NY 11021
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
331077509

2. CONTACT NAME
Maria Griffin

2.1 E-MAIL ADDRESS
maria@mdiconsultants.com

2.2 TELEPHONE NUMBER (include Area code)
516-4829001

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
516-4820186

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4) 13-Aug-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

K15 SY/A

DJA x00265

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

TABLE OF CONTENTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00266

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
1-866-999-6954 (TF)
(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

RETURN RECEIPT REQUESTED

September 5, 2008

Office of Device Evaluation
U. S. Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: 510(k) Notification

Dear Sir/Madam:

Enclosed please find an original and a copy of the 510(k) notification for the device that LIGHTWAVE Technologies LLC intends to market. The device is a LIGHTWAVE Professional Deluxe.

We would appreciate a rapid review in that we plan to distribute the product upon your approval.

If there are any questions, please contact me at (704) 843-1625. Any correspondence referring to this 510(k) submission should be forwarded to Mrs. Maria Griffin, MDI Consultants, Inc., 55 Northern Blvd., Suite 200, Great Neck, N.Y. 11021.

Sincerely,

LIGHTWAVE Technologies LLC

Maria F. Griffin /da

Maria F. Griffin
Official Correspondent for
LIGHTWAVE Technologies LLC

Enclosure

FDA CDRH DMC
SEP 8 2008
Received

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00268

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
1-866-999-6954 (TF)
(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

RETURN RECEIPT REQUESTED

September 5, 2008

Office of Device Evaluation
U. S. Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, a pre-market notification is hereby made of the intention of **LIGHTWAVE Technologies LLC** to introduce into interstate commerce for commercial distribution a Laser Instrument, Surgical powered to be known as the **LIGHTWAVE Professional Deluxe**.

The following information is being submitted in conformance with 21 CFR Part 807.87, and the FDA Guidance Document entitled: "Information required in a Premarket Notification Submission", and "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices" as follows:

Section 1 – General Information

1. **Applicant:** **LIGHTWAVE Technologies LLC**
2222 W. Parkside Lane
Suite 111
Phoenix, AZ 85027
United States
TEL: 602 548 8808
FAX: 602 548 8818

Registration No.: Not Assigned yet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00269

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

2. Contact Persons:

Ms. Maria F. Griffin
Official Correspondent for
LIGHTWAVE Technologies LLC
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021
TEL: (704) 516-8197 or (516) 482-9001
FAX: (516) 482-0186
EMAIL: Maria@mdiconsultants.com

Alternate Only:
Mike Poling
President
LIGHTWAVE Technologies LLC
2222 W. Parkside Lane
Suite 111
Phoenix, AZ 85027
United States
TEL: 602-548-8808
FAX: 602-548-8818
EMAIL: mikep@myLIGHTWAVE.com

a. Trade/Proprietary Name Including Model Number of Device:

LIGHTWAVE Professional Deluxe

b. Common Name or Classification Name (21 CFR Part 807.87) of Device:

Common Name:	laser instrument, surgical powered
Regulation:	878.4810
Product Code:	GEX
Panel:	79

Common Name:	infrared lamp
Regulation:	21 CFR 890.550
Product Code:	ILY
Panel:	89

c. Address of Manufacturing Facility/Sterilization Sites:

This device is not sterilized.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00270

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Manufacturer:

(b) (4) [redacted]

Registration No.: not assigned yet

d. Class in which Device has been placed:

Class II

e. Reason for Premarket Notification:

New Device/Introduction of a device that is substantially equivalent to a legally marketed device.

f. Name of Legally Marketed Device which We Claim Substantial Equivalence (Predicate Device) and 510(k) Number Under Which It Was Cleared.

Photo Therapeutics Ltd. K030883, K030426, K043317

g. Compliance with Requirements of the Federal FD&C Act:

This device has been classified as Class II, 21 CFR Part 878.4810 and 890.5500.

Section 2 – Summary & Certification

a. 510(k) Summary or Certification:

Please refer to Exhibit #1 "510(k) Summary", which is our summary of safety and effectiveness information upon which an equivalence determination can be based, which can be released to the public.

b. Class III Certification and Summary:

We are not claiming substantial equivalence to a Class III device, and a Class III Certification and Summary is not included.

c. Kit Certification and Information:

This device is not a kit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00271

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

d. Truthful and Accuracy Statement:

Please refer to Exhibit 2 for the "Truthful and Accuracy Statement", which has been signed by a responsible person in our company.

Section 3 – *Indications for Use*

The LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

Please also refer to the "Indications for Use Statements", which are attached as Exhibit 3.

Section 4 – Description of Device

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.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00272

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b) (4)

The following 15 programs have been designed to address the most common requested cosmetic treatments:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00273

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

1. **Is the device life supporting or life sustaining?**

   No

2. **Is the device an implant?**

   No

3. **Is the device sterile?**

   No

4. **Is the device single use or reusable?**

   Reusable

5. **Is the device for prescription use?**

   Yes

6. **Is the device for hospital, home or mobile use?**

   Mobile

7. **Does the device contain a drug or biological product as a component?**

   No

8. **Is the device a kit?**

   No

9. **Is the device software driven?**

   Yes

10. **Is the device electrically operated?**

    Yes

11. **Are there applicable voluntary standards for this device?**

    Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00274

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Section 5 – Comparison to the 510(k) Cleared Device

1. Spot Size Difference:

The slight increased spot size or coverage area allows provider/user/technician more surface area to be exposed when needed (provider dictated). This variation in size allows the treatment to be performed on individuals of various sizes. The increased spot size posses no significant concern for the safety or effectiveness of the device.

2. Programs – Wave/Duration:

LIGHTWAVE's setting for the CW waveform is equivalent to the CW protocol of the predicate Omnilux Revive. The pulsed waveform, which varies based on user selection, is within the same parameters of the named predicates. Each of the predicates uses a similar range of waveform. All of LIGHTWAVE's preset parameters fall within the predicates and pose no significant concern for the safety or effectiveness of the device.

3. Treatment Protocols:

The treatment protocols for the LIGHTWAVE Professional Deluxe are similar or equivalent to the same characteristics of the compared legally marketed devices. The treatment time is within the same parameters as predicates.

A comparison chart has been created showing the similarities and differences of the subject device to the predicate devices.

Refer to Exhibit 4 for a copy of the "Comparison Chart".

Section 6 – Proposed Labeling for the Device

The following documents are included as proposed labeling for the device:

Exhibit # 5	LIGHTWAVE Professional Deluxe User Manual and Product Spec Sheet
Exhibit # 6	Predicate Device Promotional Material
Exhibit # 7	Photo of Subject Device

Section 7 - Electrical, Mechanical and Environmental/Performance Testing

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:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00275

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

	Standard	Title
1	IEC 60601-1	**Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995**. (General)
2	IEC 60601-1-2:2001	**Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests**

Reference the following for supporting documentation:

Exhibit 8 "FDA 3654 Form for Standards"
Exhibit 9 "Bill of Materials"
Exhibit 11 "Electrical Safety/EMC Testing Documentation"
Exhibit 12 "Temperature Readings"
Exhibit 13 "Functional Test Procedure"

Conclusions Drawn from Tests and Analysis:

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 compared legally marketed devices.

Section 8 –Clinical Testing

Conclusions Drawn from Tests and Analysis:

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 compared legally marketed devices.

Clinical Performance Data:

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

Section 9 - Biocompatibility

We have assessed all of our patient contacting materials for biocompatibility requirements in accordance with the May 1, 1995 FDA Biocompatibility Guidance, the FDA-modified matrix of the "International Standard ISO-10993", "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", including the flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests of 510(k)'s.

Refer to Exhibit 9 "Bill of Materials" for a complete list of device components and materials. The device does not touch the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00276

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Section 10 – Software

The software information for this submission was compiled in accordance with the following document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Please refer to Exhibit 10 for a copy of the "Software Requirements" document.

Additional Information: Quality Assurance and Manufacturing Controls:

LIGHTWAVE Technologies LLC operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (21 CFR Part 820), and a formally established end controlled Quality Assurance Program. Devices are manufactured and assembled to established and controlled device master record requirements by formally trained and supervised personnel.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. Our intent to market this device is not considered public information and we have taken precautions to protect this confidentiality.

We would appreciate your reviewing this information at your earliest conveniences so that prompt reply to our request for clearance can be processed.

If you have any questions, or require additional information, please call me at (704) 516-8197 or (516) 482-9001. You can also reach me via e-mail at **Maria@mdiconsultants.com** or FAX me at (516)482-0186.

Sincerely,

LIGHTWAVE Technologies LLC

Maria F. Griffin /fa

Maria F. Griffin
Official Correspondent for
LIGHTWAVE Technologies LLC

MFG
Attachments (See List Attached)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00277

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

LIST OF EXHIBITS

EXHIBIT #1	510(k) Summary
EXHIBIT #2	Truthful and Accuracy Statement
EXHIBIT #3	Indications for Use Statement
EXHIBIT #4	Comparison Chart
EXHIBIT #5	Lightwave Professional Deluxe User Manual and Product Spec Sheet
EXHIBIT #6	Predicate Device Promotional Material
EXHIBIT #7	Photo of Subject Device
EXHIBIT #8	FDA 3654 Form for Standards
EXHIBIT #9	Bill of Materials
EXHIBIT #10	Software Requirements Document
EXHIBIT #11	Electrical Safety/EMC Testing Documentation
EXHIBIT #12	Temperature Readings
EXHIBIT #13	Functional Test Procedure

Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00278

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

EXHIBIT #1

510(k) Summary

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

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:	September 5, 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)

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00279

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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 Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

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

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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.

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

(As Required By 21 CFR 807.87(k))

I certify that, in my capacity as *President* of *LIGHTWAVE Technologies,* I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Michael Poling

8/28/08

(Dated)

(Premarket Notification (510(k)) Number)

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

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Exhibit # 3

Indications for Use

510(k) Number (if known): _____

Device Name: Lightwave Professional Deluxe

Indications For Use:

The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

Prescription Use X **OR** **Over-The Counter Use**
(Per 21 CFR 801 Subpart D) **(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)

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EXHIBIT #4

LED Comparison Chart & Technical Specifications

Company	**LIGHTWAVE Technologies LLC**	**Photo Therapeutics, Ltd.**	**Photo Therapeutics, Ltd.**	**SE or Different**
Device Name	**LIGHTWAVE Professional DELUXE**	**Omnilux Revive**	**Omnilux Blue**	
K Number	to be assigned	K030426	K030883	N/A
Regulation Number	878.4810	878.4810	878.4810	N/A
Product Code	GEX	GEX	GEX	SE
Light Source	LED (noncoherent) Multi diode	LED (noncoherent) Multi diode	LED (noncoherent) Multi diode	SE
Spectrum (wavelength)	630/420 nm	633 nm	415 nm	SE
Delivery	Treatment Head - LED Array	Treatment Head - LED Array	Treatment Head - LED Array	SE
Output Intensity	1 ~ 82mW/cm^2	105mW/cm2	40mW/cm2	Different
Standard Dose	Red: 133.84 J/cm2 Blue: 91.01 J/cm2	126 J/cm2	48 J/cm2	Different
Treatment Time	Up to 20 min	Up to 20 min	Up to 20 min	SE
Dose range (adjustable)	Red: 1-133.34 J/cm2 Blue: 1-91.01 J/cm2	1-150 J/cm2	1-55 J/cm2	Different
Bandwidth	Red: 25nm +/-5nm Blue 20nm +/-5nm	20 nm +/- 3 nm	22 nm +/- 3 nm	SE
Wave Form	CW & Variable	CW	CW	SE
Target Population	Individuals Suffering from indicated dermatological conditions	Individuals Suffering from indicated dermatological conditions	Individuals Suffering from indicated dermatological conditions	SE
Location for use	Prescription use	Prescription use	Prescription use	SE
Spot Size (Coverage Area)	Up to 1662 cm2	541.12 cm2	541.12 cm2	Different
Intended use	The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris.	The OmniLux Revive was cleared (K030426) for the use in dermatology for the treatment of superficial, benign vascular and pigmented lesions. The Omnilux Revive and Blue combination was cleared (K043329) for dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	The Omnilux Blue was cleared (K030883) to treat dematological conditions specifically aimed at treating mild to moderate inflammatory acne vulgaris.The Omnilux Revive and Blue combination was cleared (K043329) for dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	SE
System Type	Table top/mobile workstation	Table top	Table top	SE
Size	58 in (H) x 24 in (W)	14 in (H) x 7 in (W)	14 in (H) x 7 in (W)	Different
Electrical Supply	AC 110VAC 220VAC 50/60 Hz	AC 110VAC 220VAC 50/60 Hz	AC 110VAC 220VAC 50/60 Hz	SE
Weight	84 lbs.	26 lbs	26 lbs	Different

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Infrared Lamp Comparison Chart & Technical Specifications

Company	LIGHTWAVE Technologies LLC	Photo Therapeutics Limited	SE or Different
Device Name	LIGHTWAVE Professional DELUXE	Omnilux Plus	N/A
K Number	To be assigned	K043317	N/A
Regulation Number	890.5500	890.5500	SE
Product Code	ILY	ILY	SE
Light Source	LED (noncoherent) Multi diode	LED (noncoherent) Multi diode	SE
Spectrum (wavelength)	880nm	830nm	Minor difference
Delivery	Treatment Head - LED Array	Treatment Head - LED Array	SE
Output Intensity	1 ~ 82mW/cm^2	55mW/cm2	Different
Standard Dose	99.42 J/cm2	66 J/cm2	Different
Treatment Time	20 mins	20 minutes	SE
Dose range (adjustable)	1-99.42 J/cm2	1-80 J/cm2	Different
Bandwidth	25nm +/-5nm	30 nm +/- 5nm	SE
Wave Form	CW/Variable	CW	SE
Target Population	Individuals Suffering from minor muscle & joint pain	Individuals Suffering from minor muscle & joint pain	SE
Location for use	Prescription use	Prescription use	SE
Spot Size (Coverage Area)	Up to 1662 cm2	541.2 cm2	Different
Intended use	LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tisue and to temporarily increase local blood circulation where applied	The Omnilux Plus 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 temporarily increase local blood circulation where applied	SE
System Type	Table top/mobile workstation	Table top	SE
Size	58 in (H) x 24 in (W)	14 in. (H) x 7 in. (W)	Different
Weight	84 lbs.	26 lbs.	Different
Electrical Supply	AC 110VAC 220VAC 50/60 Hz	AC 110VAC 220VAC 50/60 Hz	SE

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EXHIBIT #5

LIGHTWAVE

THE FUTURE OF COSMETIC REJUVENATION

Professional Deluxe Model

Operator Manual and Instructional Overview

LIGHTWAVE TECHNOLOGIES
2222 W. Parkside Lane, Ste 111 Phoenix, Arizona 85027
1-866-999-6954
www.MYLIGHTWAVE.com

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NOTICE: READ BEFORE OPERATING

The information supplied throughout this document should be used only as a guideline and does not constitute or replace medical advice. LIGHTWAVE™ Technologies is registered with the FDA. The intended use of the LIGHTWAVE™ System is for cosmetic rejuvenation and has been determined by the FDA "to be of non-significant risk."

- This manual must be kept for quick reference on use, cautions, maintenance and repair.

- Read this manual in its entirety before using the LIGHTWAVE™ system.

- Improper use of the LIGHTWAVE™ system can void the warranty. Please familiarize yourself with the limitations of the warranty and proper handling and storage of the system.

- The goggles included with the LIGHTWAVE™ unit are to be used at all times while operating any setting on the system. Due to the specific protection of the safety eye wear; they should never be used as protection with any other light or laser systems. Company issued replacement plastic goggles, stainless steel framed safety glasses, and disposable LED shields have all been shown to be effective. These varieties of eye protection are available for purchase through LIGHTWAVE™ Technologies.

- Should the panel ever come in direct contact with the skin for any reason, LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol swab to avoid cross contamination. NEVER clean the panel when the unit is powered "ON."

- WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the LIGHTWAVE Professional Deluxe by children or incapacitated persons may be dangerous.

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LIGHTWAVE

Model - Deluxe

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Getting Started

LIGHTWAVE™ systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

There is no better place to begin than with a summary of LIGHTWAVE™ and its common usages. Although the system has preset programs containing the necessary settings needed to perform light therapy, it is very important to understand the basic nature of light therapy in order to maximize the results from a LIGHTWAVE™ treatment session.

Introduction

The LIGHTWAVE™ 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. Clinically there have been recorded positive therapeutic effects for over the past 40 years documented by independent research and publications worldwide. The application of LED's to tissue is non-invasive and provides a remarkable treatment alternative to traditional prescription medication and/or surgery.

While lasers and LED's have been used in medicine for years – for example, in eye surgeries and other delicate operations such as laser surgery – the scope of their full potential is just beginning to become widely known and accepted. Recent studies indicate that intense red and infrared light, which can penetrate below the skin, promotes the healing process and fuels over 20 different positive changes at a cellular level, including the production of endorphins, the body's natural painkillers.

Instructional Overview

Light is electromagnetic radiation (photons), which means that **light = particles of energy**. Many terms are used when defining light. The terms most important pertaining to light therapy are **wavelength**, **frequency**, and **power** (watts). The wavelength, in short, is the color of the light measured in nanometers. The colors of light used in the LIGHTWAVE™ Deluxe are usually red and infrared. The frequency of light is how many pulses per second the light is delivered in. The power of light is the strength or intensity of the light measured in watts or joules (i.e., 100 watt light bulb). Light therapy is very dependent upon these three characteristics of light.

As we go through our day, our bodies are bombarded by numerous wavelengths (colors) of light, all in different frequencies and different wattages.

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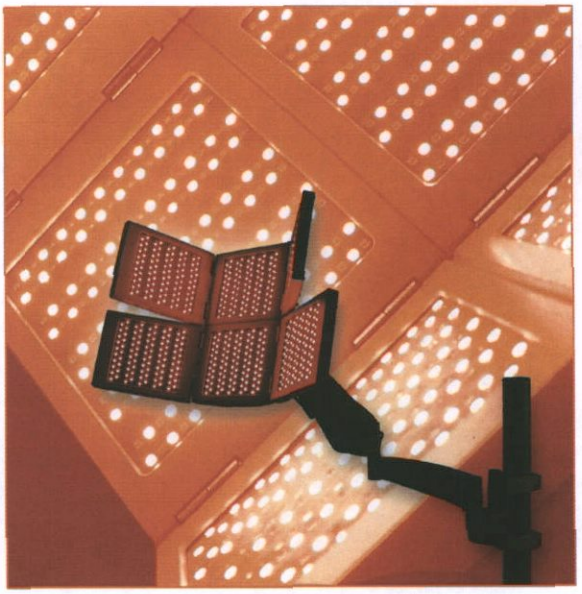
This light, which is produced mainly from the sun, affects our body's living tissue in many ways so importantly - without it, we would die. Decades ago, it was found that red and infrared light had a very positive effect on cells in human and animal bodies', with different frequencies and powers affecting cells differently. The wavelengths of light used in the LIGHTWAVE™ system (red and infrared) are very close in wavelength, the range from red to infrared being 600 to 950 nm (nm=nanometers=unit of measure for the wavelength of light) respectively. The frequencies of light used in the system are from 0 Hz to 10 KHz (Hz=Hertz=unit of measure for the frequency of light). Zero Hz is commonly referred to as a continuous wave. The powers of light used in the LIGHTWAVE™ unit are from 60% to 100% of the total watts of each LIGHTWAVE ™ pad.

How do wavelength, frequency, and power relate to light therapy?

When light (photons) is administered to tissue it is painless, hence LIGHTWAVE™ treatments are painless. Studies have shown that LED light (photons) enters the tissue, stimulates the basic cell structure and function, and significantly increases cellular activity by increasing the production of adenosine triphosphate (ATP). Thus many conditions can be "jump started" and desired results can be experienced at a much more rapid rate.



Both red and infrared light are becoming well known for their undeniable restorative benefits. When red and infrared light are administered correctly, you can expect to see many positive cellular changes; including an increase in collagen and elastin fiber production, increased vascularity, improved lymphatic system activity, a reduction in the excitability of nervous tissue and a boost in phagocytosis. Red light addresses many surface or near surface imperfections and conditions while infrared light penetrates much deeper. Certain frequencies of light stimulate cells in different ways and the power can be adjusted to give a more sensitive or more intense treatment. Mass analysis of data from documented clinical studies has allowed LIGHTWAVE™ to use pre-programmed settings to help guide the user in achieving the best possible results. All fifteen preset programs are designed to deliver enough power to stimulate a positive response from the body but do not deliver enough power to actually damage any of the surrounding tissues. LIGHTWAVE™ therapy is a safe and effective treatment with practically no known side-effects.

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Conditions Being Treated By LED Therapy Worldwide

General:

Skin Rejuvenation
Pre and Post Laser Care
Cellulite
Striae Scars
Alopecia and Thinning Hair
Hyper-pigmentation and Sun Spots

Injuries:

Rotator Cuff Tears
Carpal Tunnel Syndrome
Lower Back Problems
Tempero-Mandibular Joint Problems
Ligament and Tendon Tears
Contusions
Tissue Strains and Sprains

Inflammatory:

Tendonitis
Bursitis
Myositis
Synovitis
Plantar Fascitis
Rheumatoid Arthritis

Degenerative:

Osteoarthritis
Degenerative Disc Disease
Fibromialgia
Chronic Leg Ulcers
Muscular Skeletal Disease
Neuromuscular Disease
Injured Nerves & Bone Fractures
Whiplash Injuries
Frozen Shoulder

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LIGHTWAVE™ THERAPY, THEORY AND PROTOCOL OVERVIEW

It is important to understand basic principles of light theory so that use of the LIGHTWAVE™ system can be maximized. Remember that each individual responds differently to light…some see noticeable effects much quicker than others. For example, we treated 29 year old twins for stretch marks and the one with a healthier lifestyle responded to treatments 3 sessions faster (10 total) than her sister (13 sessions). The following principles are generalities and specific results will vary from client to client.

A) Red light (630nm-640nm) penetrates human tissue more superficially, with approximately 80% of the energy being absorbed in the first 2cm. Red light energy has a significant effect on mitochondrial stimulation, which increases the production of ATP and in turn boosts fibroblast activity. This leads to an increase in cellular turn over and superficial circulation

B) Infrared (IR) wavelength (800nm - 900nm) energy penetrates deeper into tissue. Approximately 50% penetrates to 8cm and decreases to less than 1% at 20cm (NASA study). Infrared energy is known to heat tissue and its effects are well documented for therapeutic pain management. For cosmetic applications IR stimulates the NaK+ pump which increases cell membrane permeability; facilitating equilibrium of cellular pH, while increasing nutritional absorption and elimination of waste byproducts.

C) Red and infrared wavelengths affect tissue similarly with similar effects. However, each wavelength has a more intense effect on tissues of different densities and depth.

D) Biological effects such as an increase in collagen bundles and elastin fibers are increased when red and infrared energy is used in conjunction with each other. However, the two wavelengths should never be used simultaneously due to possible wavelength interference.

E) Tissues may be affected differently by pulsing the wavelengths between 10 Hz - 10,000 Hz. Slow pulses reduce nerve sensitivity by decreasing the production of Brinikin lucitrin necessary in the transmission of pain signals. Mid range pulses stimulate endorphin production while intense pulses stimulate mitosis and cellular repair. Each program incorporates multiple pulse frequencies designed for optimum tissue response for each indication.

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Please see the LIGHTWAVE™ Theory & Protocol usage booklet for detailed protocol information. Below you will find a brief overview of each protocol.

Based on the previously mentioned principles, the following 15 programs have been designed to address the most common requested cosmetic treatments. Remember all treatments are between 15-20 minutes in duration.

1. Facial Rejuvenation – This protocol is designed to help re-hydrate the face, and increase collagen and elastin formation reducing fine lines and wrinkles. Reduces flaccidity, lifts sagging tissues and restores skin tone and structure to the totic face resulting in an overall improvement erasing years from the face. The use of goggles is recommended to minimize brightness and to avoid any incidental eye exposure. The panels are to be placed directly over the face to maximize the effects of the treatment. Ten treatments are recommended. Maintenance once a month or as needed can prolong the youthful appearance.

2. Wrinkles –This program focuses on improving wrinkles around the eyes and mouth with less emphasis on flaccidity. This program is generally used for clients with little or no signs of ptosis but with noticeable crow's feet or smokers mouth. This program should not be confused with wrinkles and flaccid skin on the neck, which should be treated with program No.7. Ten treatments are recommended.

3. Cellulite - Using intense red light, this program focuses on increasing circulation to the dermis bringing more nutrients to the area while the IR stimulates lymphatic drainage leaving the skin smooth with improved texture. Led panel should be placed directly over the cellulite area approximately ½ inch from the skin. LIGHTWAVE™ Therapy can help control cellulite when applied regularly and followed up by monthly maintenance. A client is always encouraged to compliment treatment with a balanced diet and moderate exercise.

4. Scars – This program is designed with intense Infrared light to stimulate the reduction of fibrotic tissue and the replacement of normal tissue. Clients usually notice softening of scar tissue in one or two sessions. They also notice flattening of the scar and sometimes they are alarmed because they see the scar appearing to become wider. This is a normal sequence in scar reduction. With several more sessions the flat wide scar will become thinner and remain flat. Some scars may appear to be resistant to this program (hypertrophic and/or keloid). If this is the case, a customized LIGHTWAVE™ treatment protocol and/or additional treatment options may need to be considered.

5. Stretch Marks - Superficial - This program is intended to reduce sub dermal scarring while stimulating superficial circulation, reducing flaccidity and thickening the thin, paper-like characteristics of stretch marks. This setting is effective with new and old flat stretch marks. Thicker/denser stretch marks should be treated with Program No. 6 - Stretch Marks II Deep. Often this program is combined with Program No. 6 after five - ten sessions and the flattening of deep stretch marks has been achieved. For flat stretch marks alone, ten - fifteen sessions are required. Darker, thick skin may require slightly more sessions. The treatment panel should be placed directly over the stretch marks approximately ½ inch from the skin.

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6. Stretch Marks - Deep - This program is designed to help break down the denser sub dermal scarring. It assists in softening and flattening thick stretch marks. Often with a series of stretch mark treatments you will need to use this program ten times followed by Program No. 5 (Superficial). Again, darker skin may require slightly more sessions. Treatment panel should be placed directly over the stretch marks approximately ½ inch from the skin.

7. Flaccid Skin -This program focuses on skin retraction by increasing circulation and bringing nutrition to damaged tissue. This program is particularly effective over the abdomen, neck and upper chest. Treatments should be applied twice per week and may require between ten - fifteen treatments. Place the panel directly over the treatment area approximately ½ inch from the skin.

8. Sun Spots - This program is intended to improve discoloration caused by sun damage, chemical build-up, and chemical reactions from chemical peels, and excessive use of skin damaging products. This process normalizes the melanin of the skin. The amount of treatments needed vary depending on the amount of damage to the skin, the thickness of the skin and the age of the client. Mild conditions will require ten - twelve treatments. Moderate conditions will require approximately fifteen - twenty treatments and severe conditions may best be treated with a combination therapy of IPL and/or laser followed by LIGHTWAVE™ Therapy.

9. Blemishes - This setting is intended to normalize dry, oily, redness associated with problem skin. It also reduces the borders (disparities between scars and normal skin), achieving evenness of texture and color. This process may require ten or more treatments.

10. Acute Discomfort - This program is specifically designed to address inflammation associated with trauma and/or an allergic reaction that causes discomfort. It is usually used within 72 hours of any traumatic event including post-surgical interventions to reduce scarring and encourage normal tissue formation. Caution should be taken where superficial circulation has been compromised.

11. Chronic Discomfort – This setting was developed with a focus on clients who experience persistent problems such as joint and muscle discomfort. Caution should be taken when treating clients with sensitive thin skin as this program induces a significant increase in tissue temperature. To alleviate discomfort, place the panel directly over the affected area approximately ½ inch from the skin.

12. Hair Growth – This program is designed to increase superficial circulation to the capillaries and scalp area, improving the health of the hair (shine, thickness and fullness) as well as the hair follicle itself. However, if the hair follicle has been in the resting phase for a long period of time and does not show any signs of growth, it is very unlikely a client will respond favorably to the treatments and that hair growth will occur. It is important to treat thinning hair as soon as possible in order to keep blood flow and nutrients moving to the dormant hair follicles. This program is often used as a follow-up for hair transplant patients.

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13. Color I *Only Red* – This program is only 15 minutes in duration and consists of red light only. Most of the energy from the red light is absorbed by the mitochondria, increasing the production of ATP. This protocol is designed to be used to treat uneven skin tone and texture, large pore size, redness, and edema on the skin's surface as well as superficial skin imperfections. This program allows the user the ability to customize a treatment protocol that has not previously been addressed by one of the other treatment settings.

14. Color II *Only IR* –The solid IR light is often used as a pre-cursor for surgical patients as well as post operative for many ablative procedures. It has been shown to stimulate specific cell lines which are needed to accelerate the healing process and minimize any scarring that may be associated with these procedures. It is suggested that two-three treatments are administered weekly until the skin no longer displays discomfort and the redness starts to subside. Once this has happened, continue to address the client's concerns with the scar setting or the chronic setting. This protocol may be used on patients who have recently had other facial treatments and find the skin to be extra sensitive to the touch. This program allows the user the ability to customize a treatment protocol that has not previously been addressed by one of the other treatment settings. This setting provides more infrared-light than programs 1-12. As a result, this program is only 15 minutes in length.

15. MAX Power/Facial Rejuvenation – This program has the same functions/parameters as the Facial Rejuvenation Program (#1), but it delivers the treatment with more intensity. This will allow for quicker results. Some light sensitive clients may not be able to use this protocol because of its intensity. If, in spite of using the protective eyewear, the client cannot tolerate the brightness, you should use the facial rejuvenation protocol.

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Operating Instructions

Deluxe System Contents

1 – Control Unit
2 – Control Unit Keys
1 – 6ft Power Cord
1 - Stand with Casters and 2 Trays
1 - Arm with pole bracket
2 - 3 pc LED arm panels
1 - LED panel main cable
1- Power Surge Protector
1- Protective Eye Wear

To Get Started

Image 1 - All LPCU's come equipped with a 4-amp fuse to protect the unit from surges. Always disconnect power before accessing fuse.

Place the LIGHTWAVE™ Professional Deluxe Control Unit, (LPCU) on the LIGHTWAVE™ stand, if you have not done so already. A rollaway table is ideal. To turn on the LIGHTWAVE™ unit, connect the female end of the electrical power cord to the back of the unit. Plug the male connector into the **surge protector,** which needs to be connected to a standard 110v electrical outlet. Next, flip the On/Off switch to the **on (-)** position on the back of the LPCU (See picture on the left).

Connecting the Arm Assembly to the Base Unit

In order to connect the LED arm assembly to the socket receiver ports on the LPCU, the operator must first identify the RED dot on the collar of the diode pad connector tip. The red dot aligns pointing directly upwards when connecting the arm to the base unit. After connecting the arm cord to the base unit, the cord needs to be connected to the arm panel. When connecting the arm cord to the arm panel, the red dot aligns pointing directly downwards instead of upwards as it did when you connected the cord to the base. After connecting the arm panel the operator can proceed to turn ON the power switch if it has not already been done, which is located on the back side of the LPCU. Upon starting, the unit will move through a number of initial screens that identify the machine's version of software and the model number. Then the control screen will indicate the present status of each socket. R12DPA indicates the arm panel is connected.

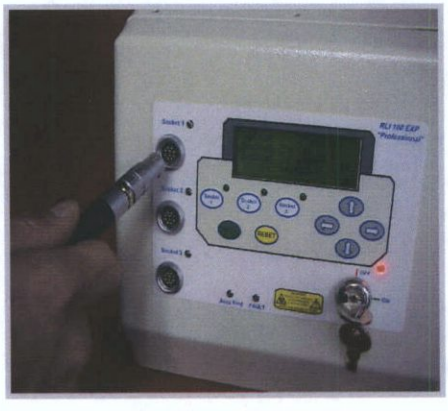

Image 2 –Be sure the red dot is pointing directly up before inserting the connector into the socket port.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

11

DJA x00296

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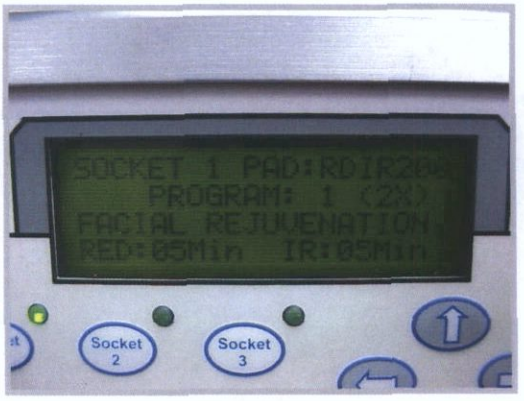
Setting the Preset Programs

When the panel is connected to the LPCU, the green indicator nearest to the corresponding socket button is illuminated indicating a good connection between the panel and the LPCU (if you have correctly connected the panel and the green light is not lit, please consult Tech Support).

Image 3-The ***Main Control Display*** *pictured to the left shows that a main panel is plugged into socket one and the green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button that corresponds to the panel that has just been connected will bring up the **Socket Status Display** for that socket. The socket status display should appear as below.

Image 4-The ***Socket Status Display*** *pictured to the right shows that a main panel is plugged into socket one. The green light next to the socket one button indicates that socket one is ready.*



Pressing the socket button again brings a blinking cursor to the program number. Using the up and down arrow keys allows the user to change from one program to the next. When the desired program is displayed, press enter, the blinking cursor will go away and the LIGHTWAVE™ unit is now ready to begin a treatment session.

Using the Machine "LOCK" Option

Some people may want to restrict the use of the machine from other users. By simply turning the key to the "OFF" position, the display will read "LOCKED" and no operations can be performed, disabling the LIGHTWAVE™ unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00297

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Using the "MENU"

The MENU can only be accessed from the **Main Control Display**. By pressing the RESET button the user is sent to the Main Control Display screen. With the arrows blinking on either side of the word "MENU", press the ENTER button and the words similar to below will be shown. (Each one of the MENU options can be accessed by moving the blinking arrows with the up and down arrow keys.)

SET TIME AND DAY: Simply use the up and down arrow keys, along with ENTER to set the time and date.

ADD TREATMENTS: This function is for the units that are contracted on a pay per treatment program or other contract. Call Tech Support when using this menu.

RETURN: Returns the display to the Main Control Display.

Performing Treatments

Starting Treatment

Note: When the LPCU detects an arm in any one of the socket ports, a green indicator light will illuminate under the control screen membrane corresponding to the connected socket (See image 3, pg. 11). If this is not illuminated, and the arm panel is correctly connected, please call for technical support.

Please follow these simple steps when performing a treatment:

1. Gently place the panel as close as comfortably possible to the patient (approximately 1-2 inches) from the area(s) selected for treatment.

CAUTION: Never have the panel placed directly on open wounds, sunburns, or sensitive tissue. Wrapping, sitting on, or restricting airflow greatly increases the panel temperature. It is important to let the panel breathe. If you place the panel directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

2. Select the treatment program corresponding to the desired treatment area. Make sure the monitor exhibits the Socket Status Display screen (See image 4, pg. 11) by pressing the corresponding socket button to the matching treatment socket.

3. Confirm the proper program is displayed, and then press ENTER. The Red indicator should light next to the socket that corresponds to the socket that was just started. As long as the Red indicator is lit, this socket is active. Do not remove the arm panel until treatment. If a patient feels uncomfortable in any way proceed with the following - **Note: To Stop a Treatment, Press "RESET" button in the Socket Status Display Screen.** For multiple treatments, simultaneously, repeat above procedures for other sockets.

DJA x00298

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PLEASE NOTE:

Eye shields are provided for patient comfort. LIGHTWAVE™ LEDT does not pose any significant risk to eye injury. Eye shields are in full compliance with U.S. Federal Law 21 CFR 1040.20 Performance Standards for Sunlamp Products.

▲ CAUTIONS

- ALWAYS USE YOUR SURGE PROTECTOR! Static electricity can cause harm to your system.
- To prolong the life of your LIGHTWAVE™ unit, never unplug the arm panel when in operation.
- Do not operate on wet surfaces.
- Avoid placing any liquids on top of unit at any time. DO NOT use if liquid has been spilled for at least 48 hours.
- Please advise your patients that it is common for some patients to increase their liquid intake while undergoing LIGHTWAVE™ treatments.
- Never lay the arm panel directly on open wounds, sunburns, or sensitive tissue. The patient should also never lie directly on the panel, restricting airflow. Never apply pressure to the arm panel. By doing so, airflow can become constricted and possible irritation or burning of the skin can occur.

NEVER open the unit. Opening the unit will void all warranties and permanently damage the programming of the system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00299

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APPENDIX

Preset Programs

Program Number	*Program*
1	Facial Rejuvenation
2	Wrinkles
3	Cellulite
4	Scars
5	Stretch Marks 1 Supr.
6	Stretch Marks 2 Deep
7	Flaccid Skin
8	Sun Spot
9	Blemishes
10	Acute Discomfort
11	Chronic Discomfort
12	Hair Growth
13	Color 1 only Red LED
14	Color 2 only IR LED
15	Max Power

LED Specifications

IR LED (LLL) = 880 nm, one Therapy Panel puts out from 110-158mw/cm2 depending upon power setting

Red LED = 630nm, one Therapy Panel puts out from 120-165mw/cm2 depending upon power setting.

Trouble Shooting

Display Freezes – Reset machine by turning main unit off for 30 seconds, then back on.

Black Boxes Appear Across Display Screen - unplug the power cord from the back of the main unit and wait at least 60 seconds before reconnecting it. Then power it up as usual.

Displays "Call Tech Support" – Call tech support at 1-866-999-6954.

LPCU Keeps Asking For Confirmation Number – Call Tech Support for code.

HELP DESK PHONE NUMBER / TECHNICAL SUPPORT

Call help desk at 1-866-999-6954 if ERROR message is displayed or other problems occur.

DJA x00300

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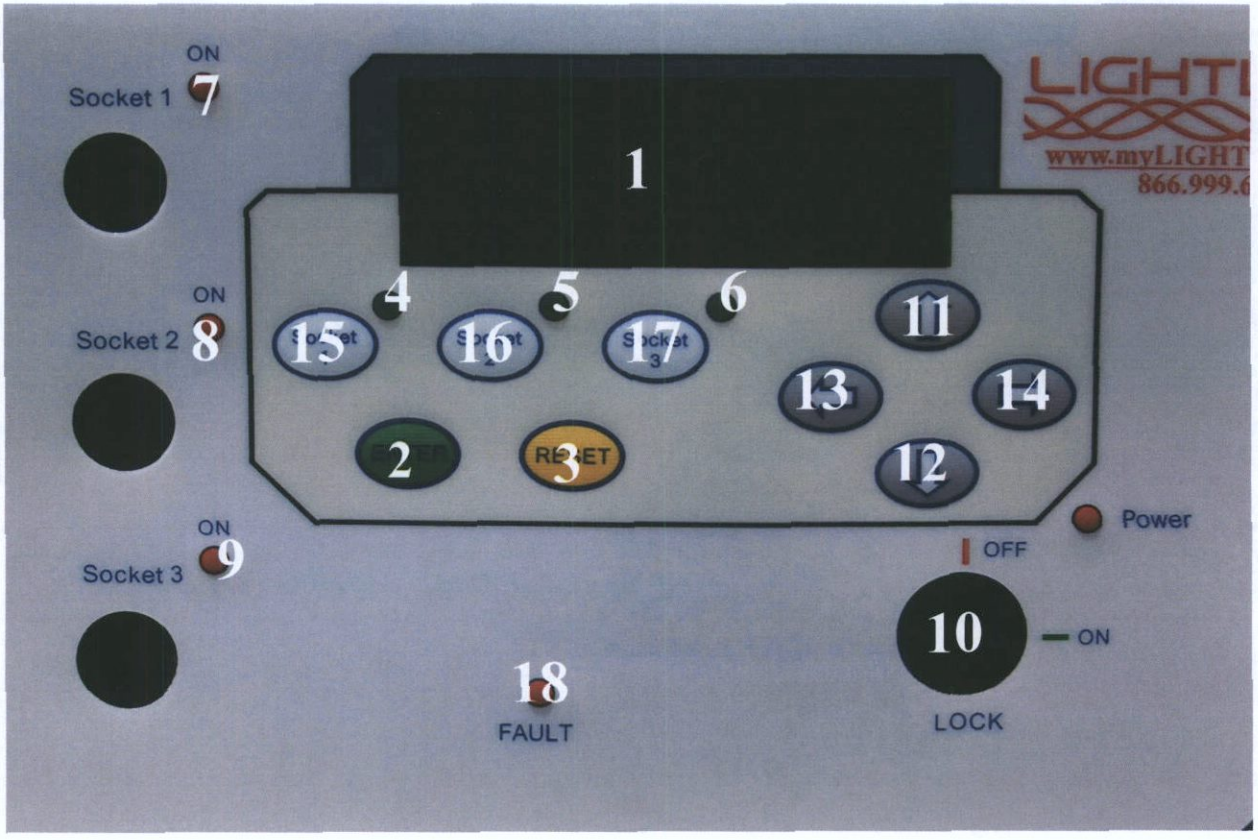
Control Unit Membrane Index

MEMBRANE CONTROL SCREEN



1. LCD Display
2. Enter Button
3. Reset Button
4. Socket 1 Display Status Button
5. Socket 2 Display Status Button
6. Socket 3 Display Status Button
7. Socket 1 and Socket 1 Active Indicator
8. Socket 2 and Socket 2 Active Indicator
9. Socket 3 and Socket 3 Active Indicator
10. LOCK
11. Up Arrow
12. Down Arrow
13. Left Arrow
14. Right Arrow
15. Socket 1 Button
16. Socket 2 Button
17. Socket 3 Button
18. Fault Indicator

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00301

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EXHIBIT #6

OMNILUXMEDICAL

Unit Specifications

Omnilux revive™

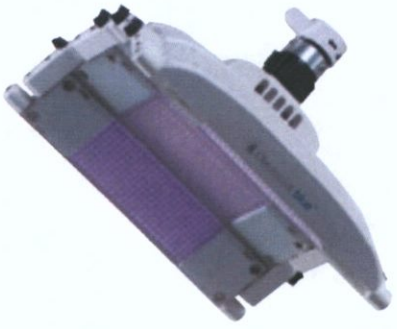
Can be used alone for primary skin rejuvenation* and in combination with Omnilux plus™ for wound healing*, psoriasis* and for the reduction of periorbital wrinkles. Can be used in combination with 5-ALA for the treatment of non-melanoma skin cancers* and severe acne*. Used in combination with Omnilux blue™ for mild to moderate acne vulgaris and cystic acne*.

Output Intensity	105 mW/cm^2
Output wavelength	633 +/- 6 nm
Standard Dose	126 J/cm^2
Treatment time (standard dose)	20 minutes
Dose range (adjustable)	1-150 J/cm^2
Bandwidth	20 nm +/- 3 nm
Weight	26lbs
Unit dimensions (H x W x D)	14" x 7" x 19"
Head dimensions overall (L x W)	12.5" x 11"
Dimensions of LED head active area (L x W)	6" x 11"

Omnilux blue™

Can be used for mild to moderate acne and cystic acne* in combination with Omnilux revive™ or in combination with 5-ALA for severe acne* and solar keratosis*.

Output Intensity	40 mW/cm^2
Output wavelength	415 +/- 5 nm
Bandwidth	22 nm +/- 3 nm
Standard Dose	48 J/cm^2
Treatment time (standard dose)	20 minutes
Dose range (adjustable)	1-55 J/cm^2
Weight	26lbs
Unit dimensions (H x W x D)	14" x 7" x 19"
Head dimensions overall (L x W)	12.5" x 14"
Dimensions of LED head active area (L x W)	6" x 14"



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00302

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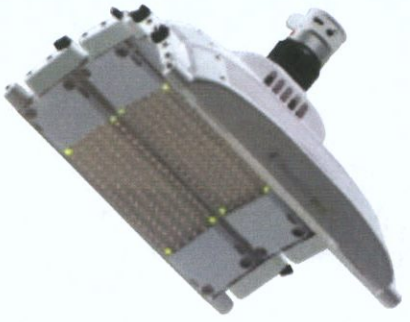
Omnilux plus™

Can be used in combination with Omnilux revive™ for periorbital wrinkles, wound healing* and psoriasis*. Effective alone for muscular pain.

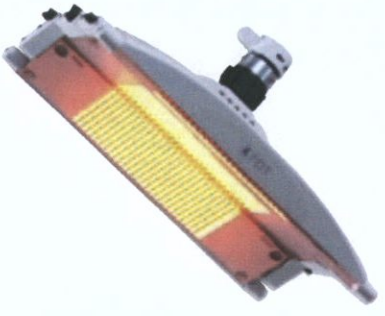
Output Intensity	55 mW/cm²
Output wavelength	830 +/- 5 nm
Standard Dose	66 J/cm²
Treatment time (standard dose)	20 minutes
Dose range (adjustable)	1-80 J/cm²
Bandwidth	30 nm +/- 5 nm
Weight	26lbs
Unit dimensions (H x W x D)	14" x 7" x 19"
Head dimensions overall (L x W)	12.5" x 14"
Dimensions of LED head active area (L x W)	6" x 14"



Omnilux PDT™

Can be used for non melanoma skin cancers in combination with 5-ALA*.

Output Intensity	80 mW/cm²
Output wavelength	633 +/- 3 nm
Bandwidth	20 nm +/- 3 nm
Standard Dose	96 J/cm²
Treatment time (standard dose)	16 minutes 40 seconds
Dose range (adjustable)	1-130 J/cm²
Weight	26lbs
Unit dimensions (H x W x D)	14" x 7" x 19"
Head dimensions overall (L x W)	15" x 8"
Dimensions of LED head active area (L x W)	9" x 8"



*Investigational device

OMNILUXMEDICAL

Photo Therapeutics INC
26429 Rancho Parkway #115
Lake Forest, CA 92630 USA
Tel. +1 949-273-5040
Fax line. +1 949-273-5044
www.phototherapeutics.us

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

EL1527

DJA K00303

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EXHIBIT #7

PHOTO FRONT

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DJA x00304

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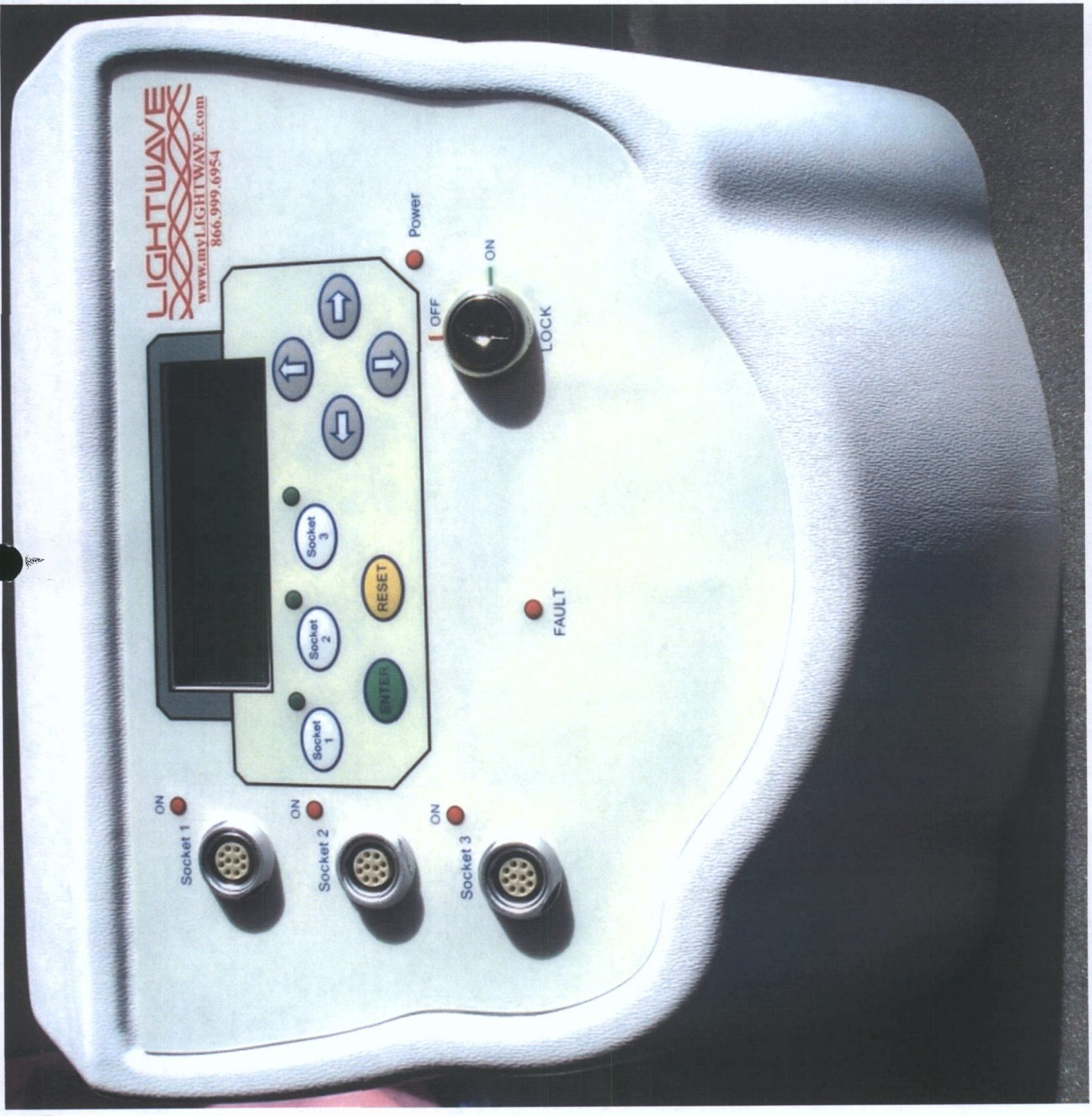
EXHIBIT #7



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00305

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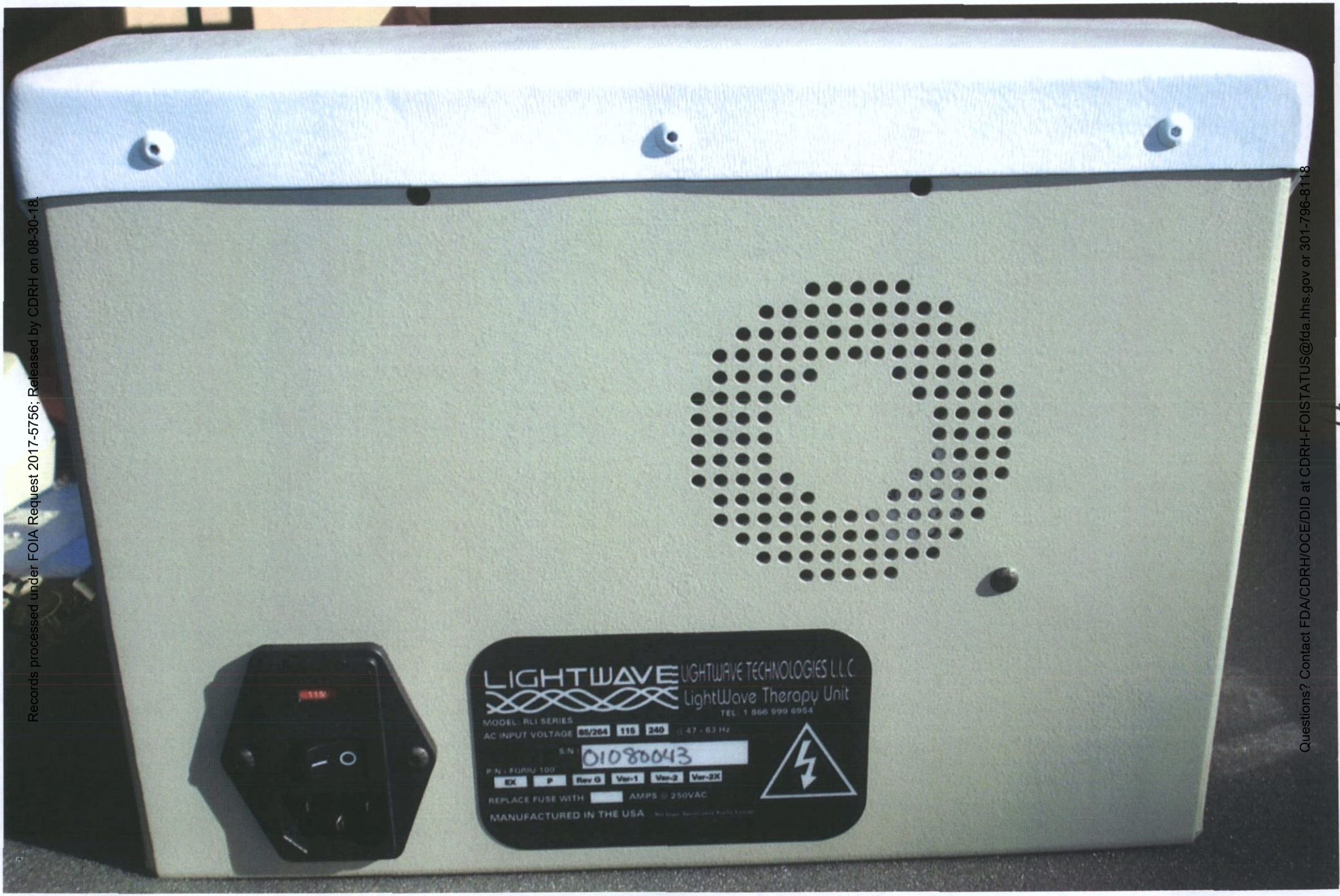
PHOTO BACK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00307

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PHOTO R SIDE OF DEVICE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00308

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00309

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PHOTO LABEL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00310

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00311

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PHOTO PANEL ACCESSORY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00312

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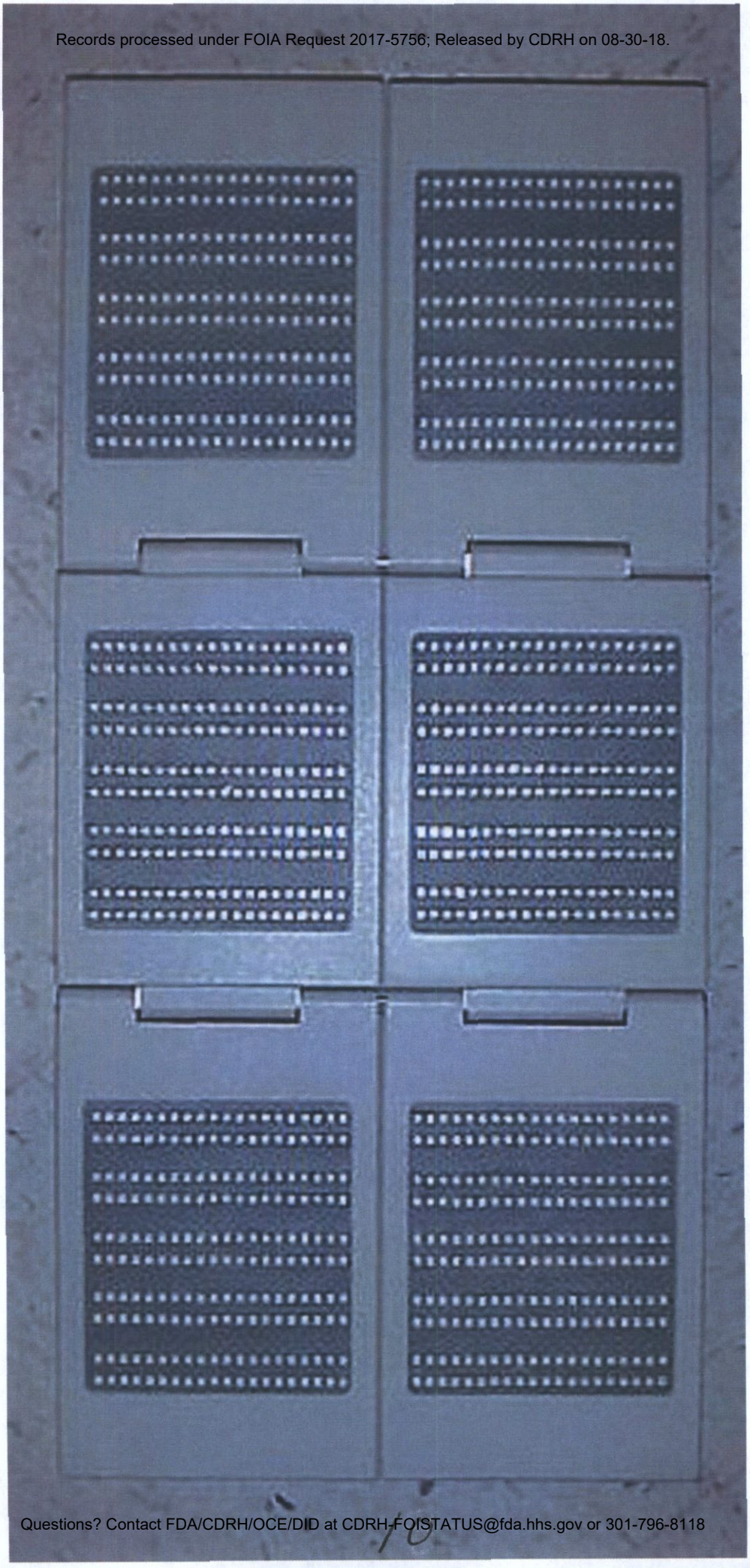

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00313

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EXHIBIT #8

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1] IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1998; Amendment 1, 1991-11, Amendment 2, 1995 (General)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00314

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EXHIBIT #8

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-30		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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DCA x00315

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EXHIBIT #9

Lightwave Technologies LLC
2222 W Parkside LN Suite:111
Phoenix, AZ 85027

BOM Deluxe Unit Rev.J

QTY:	P/N:	LIGHTWAVE P/N:	Description	Vendor:	Manufacturer:
(b) (4)					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00316

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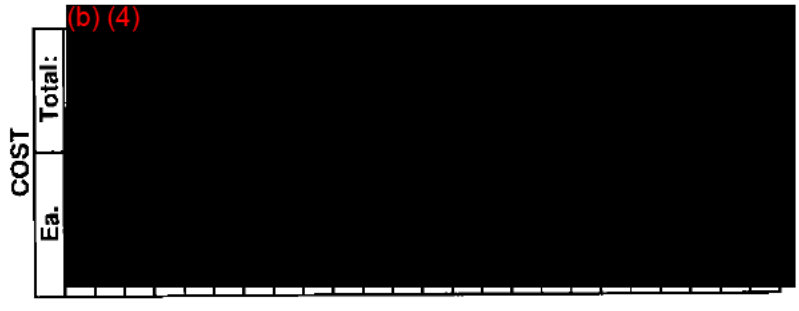

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00317

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EXHIBIT #10

SOFTWARE INFO

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00318

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Software Requirements Specification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00319

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Table of Contents

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DJA x00320

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(b)(4)

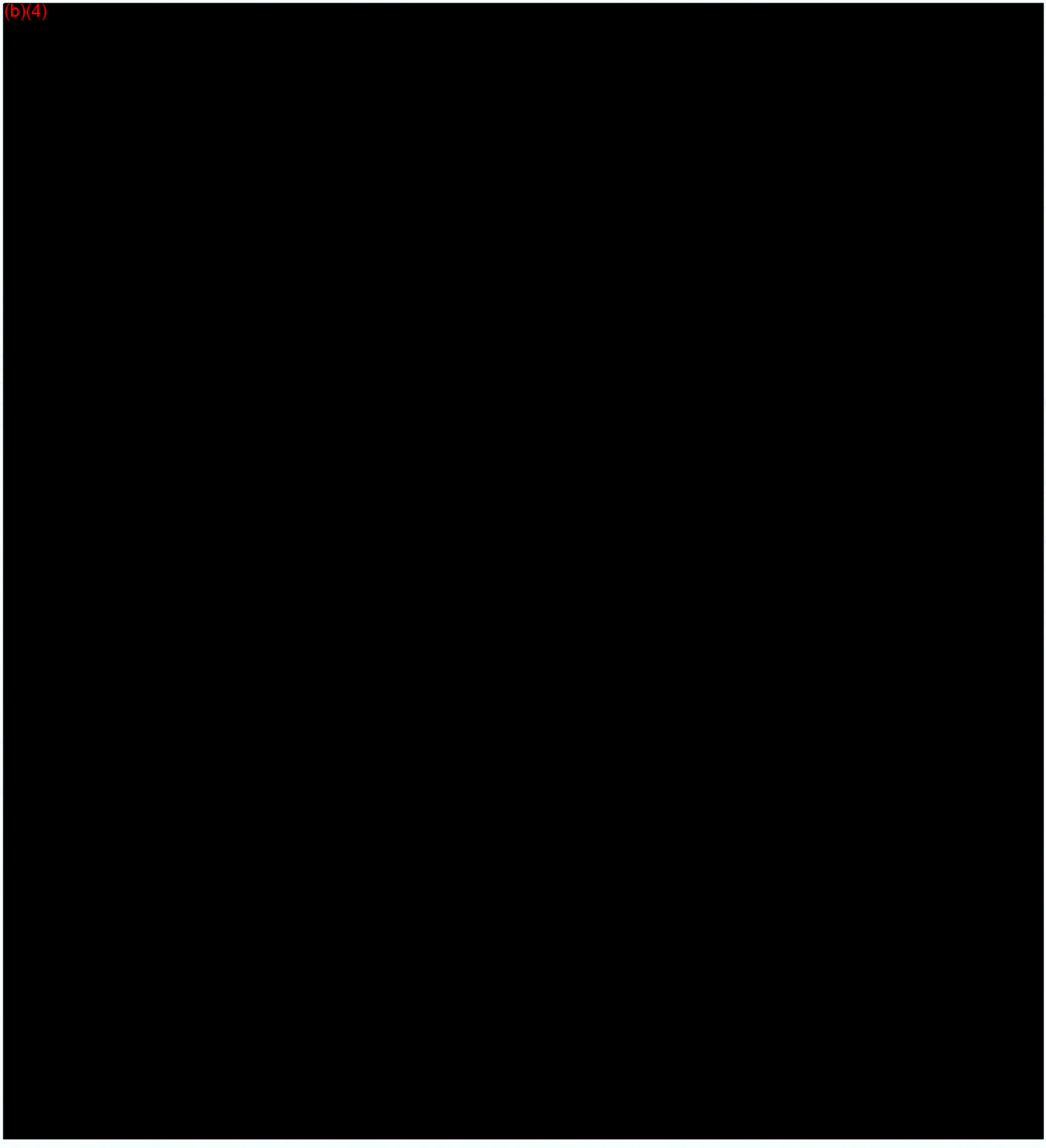
[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00321

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)



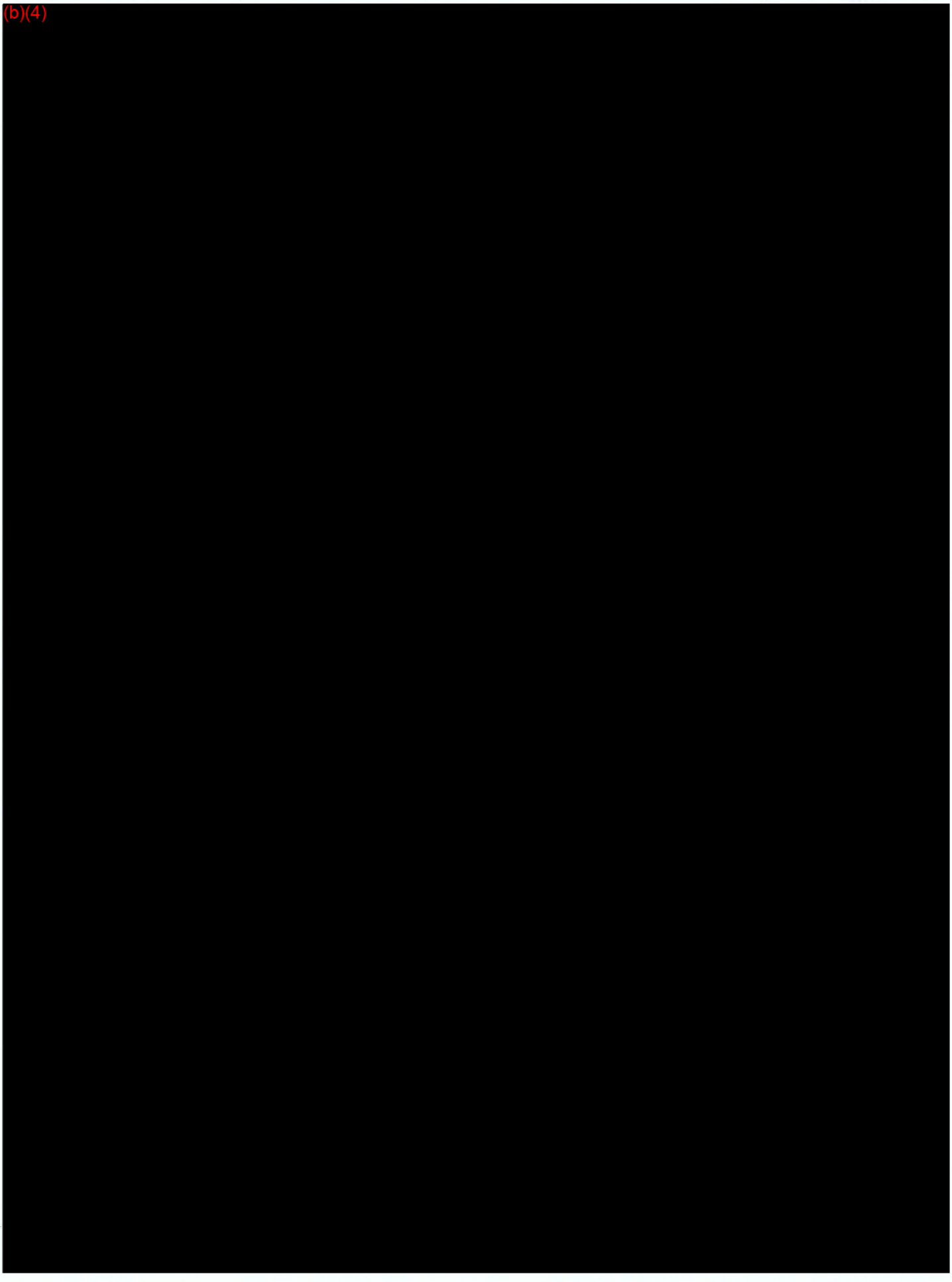
DJA x00322

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

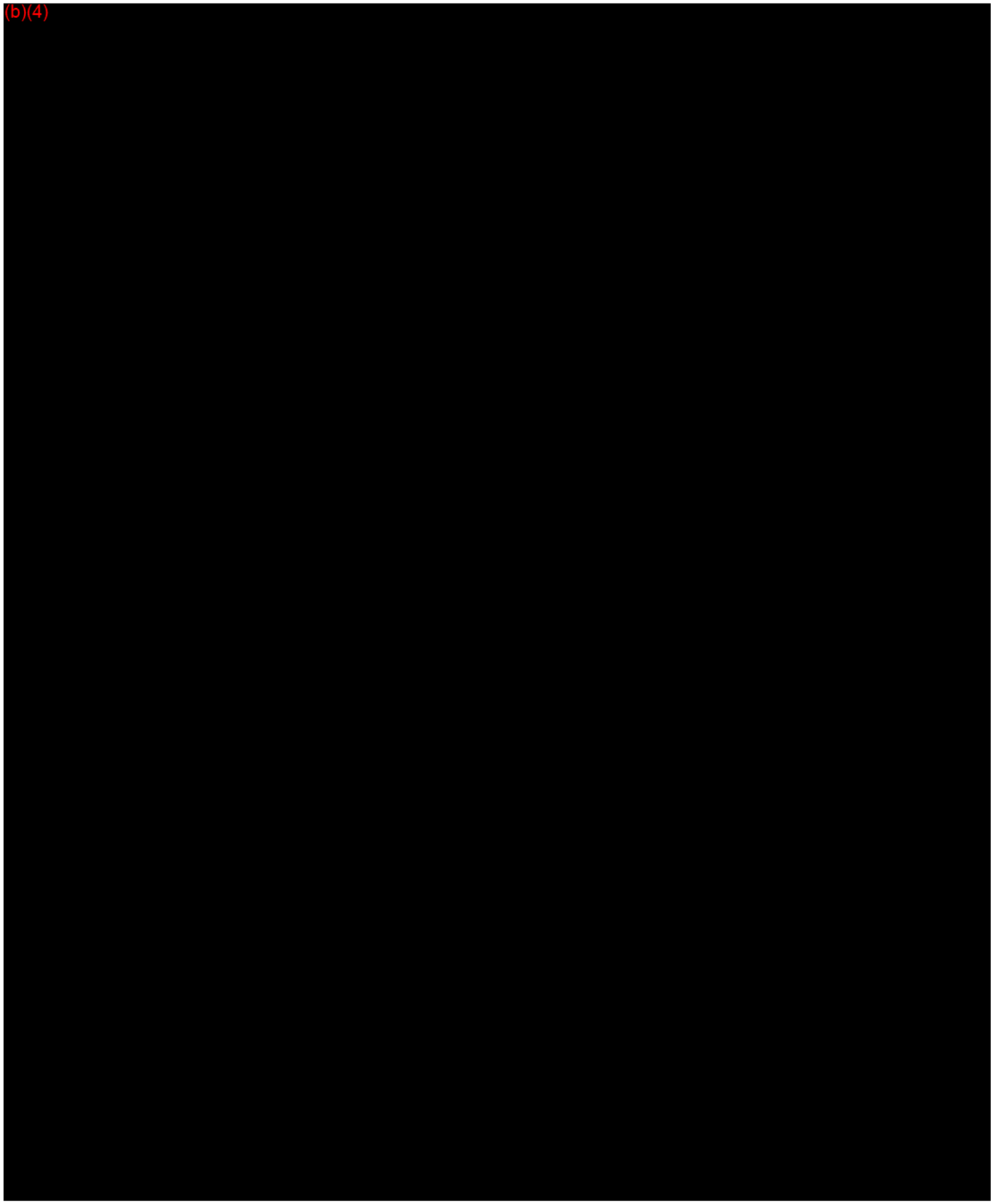
DJA x00323



DJA x00324

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)

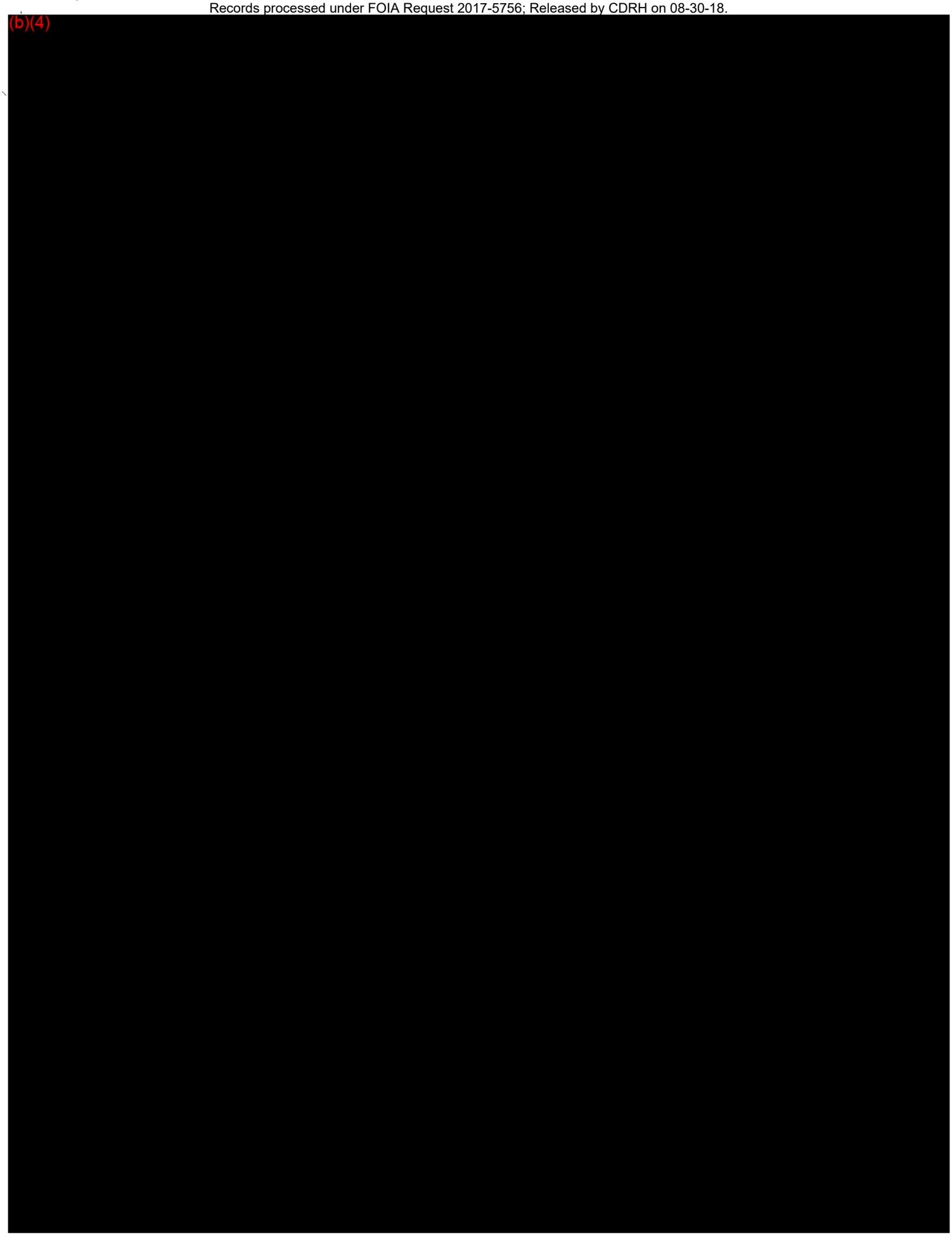


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00325

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)

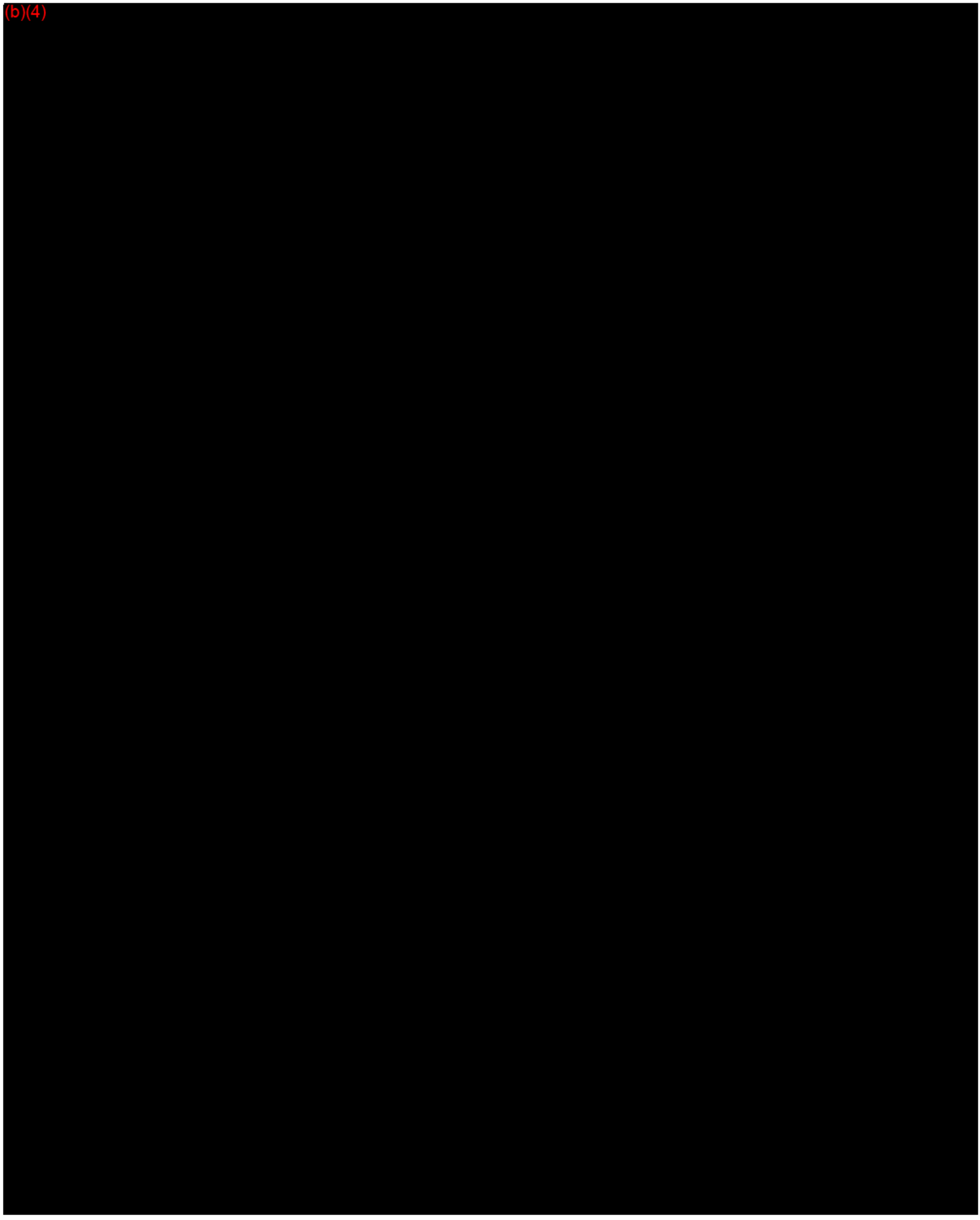


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00326

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)

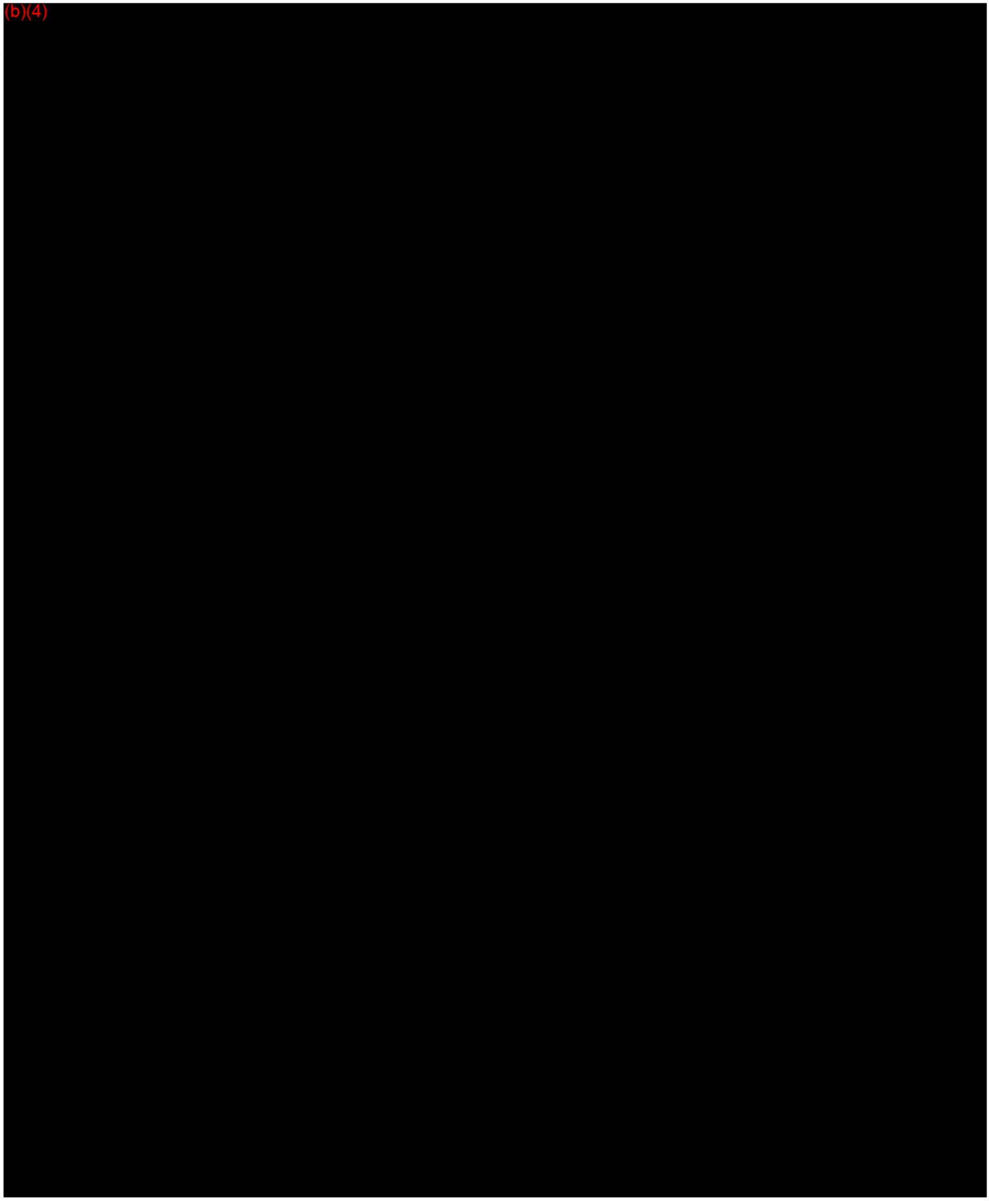


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00327

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00328

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00329

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

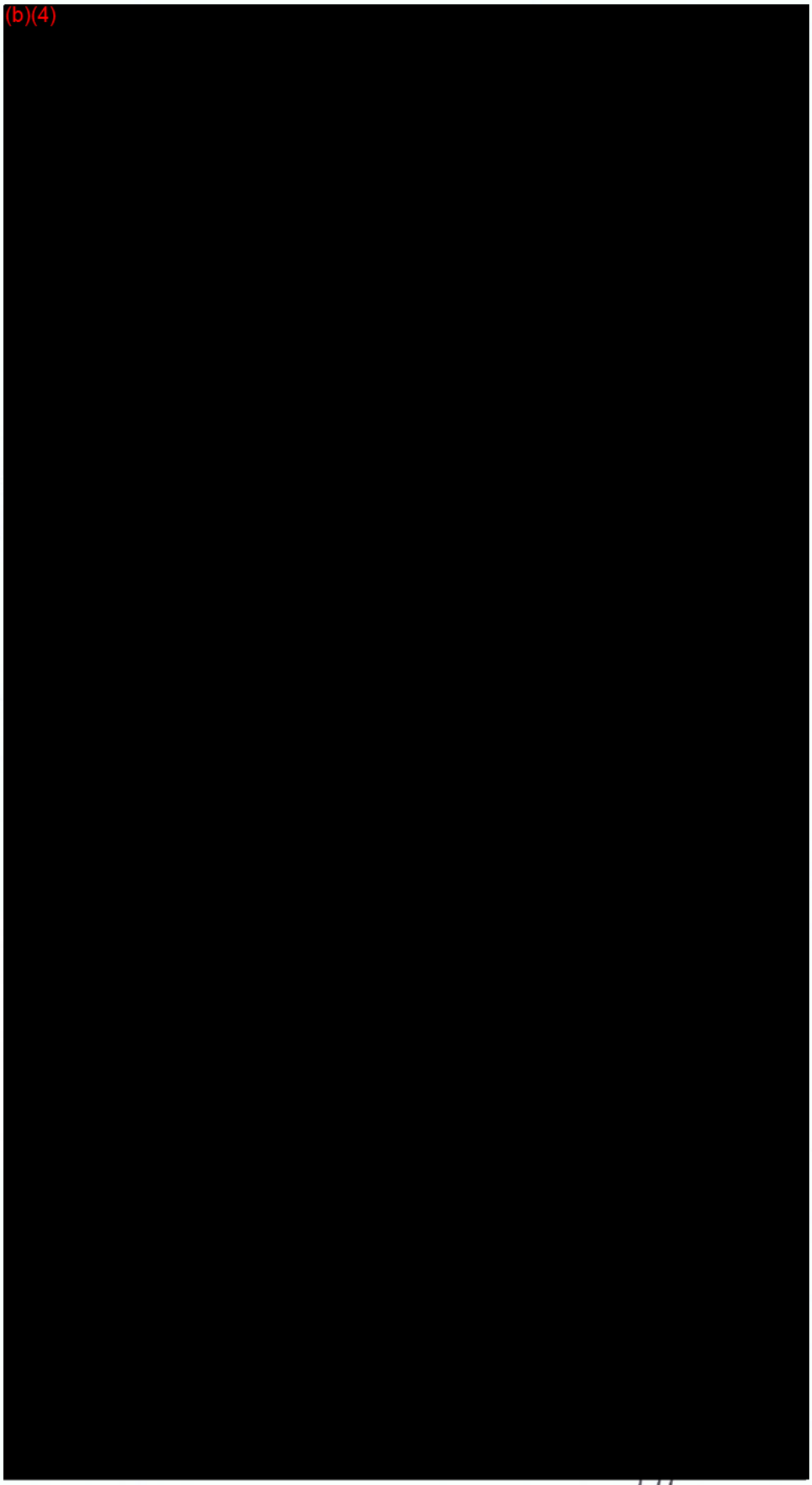
SOFTWARE TEST SUMMARY
LW FREQ&DURATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00330

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00331

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

EXHIBIT #11

IEC 60601-1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00332

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

EXHIBIT #11

LVD Test Data (b)(4) for:

IEC60601-1
Clause 19 Continuous Leakage Currents
Clause 20 Dielectric Strength
Clause 21 Mechanical Strength

Customer:
LightWave Technologies
2222 W. Parkside Lane #111
Phoenix, AZ 85027

EUT Description: LED Lamp

EUT Model Number(s):
RLI

Third Party Test Laboratory:
(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

DJA x00336

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

IEC 60601-1-2 2001

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00337

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

IEC 60601-1-2 2001

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00338

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Electromagnetic Compatibility

Test Report for the

LED Lamp

Model # RLI Series

Test Report Number (b)(4)

Prepared For:
LightWave Technologies
2222 W. Parkside Lane, #111
Phoenix, AZ 85027

Prepared by:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00339

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

12 Feb 2008

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00340

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Test Data

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DJA x00004

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name RICHARD WEIBLINGER

Subject: 510(k) Number K062586/S3

To: The Record

Please list CTS decision code SE

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

7/2/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DJA x00005

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number **Class*** **Product Code**

Class II GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Richard P Bellen (Branch Chief) GSNB (Branch Code) 1-4-2010 (Date)

Final Review: Mark N Melkerson (Division Director) 1/4/10 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00006

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K082586s3

Date: December 15, 2009
To: The Record
From: Richard Paul Weiblinger, M.P.H.

Office: ODE

Division: DSORD

510(k) Holder: Lightwave Technologies, LLC.
Device Name: LIGHTWAVE™ Professional Delux LED system
Contact: Maria Griffin or Mike Polling c/o MDI Consultants, Inc.
Phone: 704-516-8197 or 516-482-9001 or 602-548-8808 or 602-738-4226 (cell)
Email:

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce LIGHTWAVE™ Professional Delux LED system into interstate commerce. The device is an LED diode panel array operating at 420 nm (visible blue), 630nm (visible red) for the treatment of acne, for the treatment of vascular and pigmented lesions (630 nm red), for the treatment of periorbital wrinkles (630 nm red and 830 nm IR), and 830 nm (near infrared) for topical heating. The firm is now responding to FDA's request for additional information.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

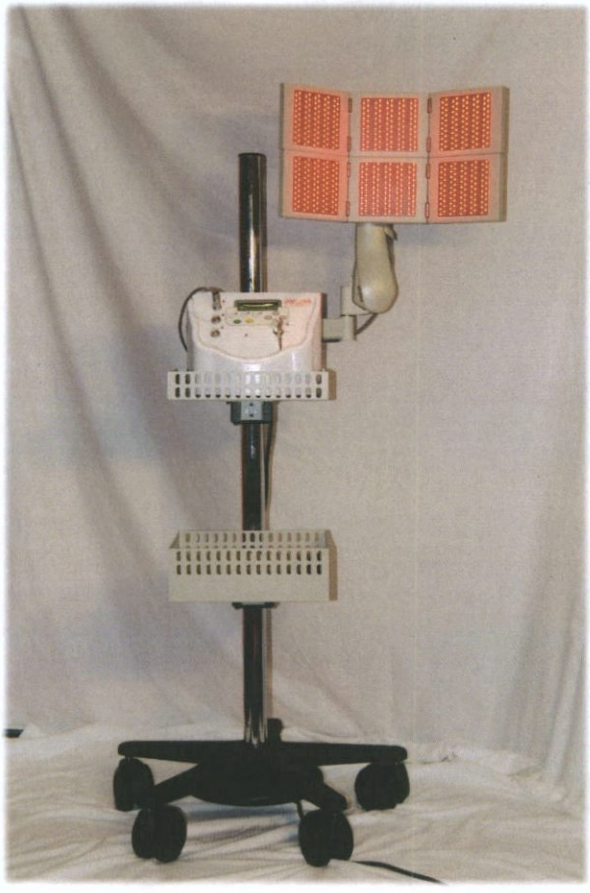
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?			

DJA x00007

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

The *LIGHTWAVE™ Professional Delux LED System consists of*

- *LED panels which can be configured to contain 1,2, or 3 rows of LED's (600, 1200, or 1800 LED's)*
- The customer has the option of purchasing the following sets of LED accessories; 1. Red and blue LED panels; 2. Red and infrared LED panels, or, 3. Red, blue and infrared LED panels.
- The system has 15 pre programmed software modules designed to address specific treatments



IV. Indications for Use

The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the Red and infrared spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles.

The indications for use encompass previously granted indications for use for this device type. This is adequate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00008

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

V. Predicate Device Comparison

A **comparison** of characteristics, features and technical specifications as compared to those of the predicate devices is provided below. The specifications for use for the new device are SE to the predicate devices.

Table 1. Red and IR comparison

Device Characteristic	*LIGHTWAVE™ Professional Delux LED System* K082586	Photo Therapeutics Omnilux New U K072459	PhotoTherapeutics Ltd. Omnilux Revive K050216	Photo Therapeutics, Ltd. Omnilux Plus LED device K043317
Indication	Topical heating (IR) Periorbital Wrinkles (red/IR)	Periorbital wrinkles (OTC)	Periorbital wrinkles	Topical Heating
Light Source	LED	LED	LED	LED
Dose Range (J/cm^2)	1 – 168.29 (red) 1 - 86.4 (IR)		1 – 150 (red) 1 – 80 (IR)	1 – 99.42 (IR)
Wavelength (nm)	630 (red) 880 (IR)	633 (Red) 839 (IR)	633 (red) 839 (IR)	830 (IR)
Standard Dose (J/cm^2)	134.63 (red) 69.12 (IR)		96 (red) 66 (IR)	66 (IR)
Dose rate (mW/cm^2)	112 (red) 57 (IR)	70 (red) 55 (IR)	105 (red) 55 (IR)	55 (IR)
Spot Size (coverage area cm^2)	Up to 1662			541.2
Treatment Time (minutes)	20 (1200 sec)	30 (1800 sec)	20 (1200 sec)	
Total Dose J/cm^2	134.4 (red) 98.4 (IR)	126 (red) 66 (IR)	126 (red) 66 (IR)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00009

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Table 2. Red and Blue comparison

Device Characteristic	*LIGHTWAVE™ Professional Delux LED System* K082586	Photo Therapeutics Omnilux Revive K030426	PhotoTherapeutics Ltd. Omnilux Blue K030883	PhotoTherapeutics Ltd. Omnilux Red and Blue K043329
Indication	Acne (red/blue) Vascular and Pigmented lesions (red)	Vascular and Pigmented lesions (red)	Acne (blue)	Acne (red/blue)
Light Source	LED	LED	LED	LED
Dose Range (J/cm^2)	1 – 168.29 (red) 1 - 67.5 (blue)	1 – 150 (red)		1 – 150 (red) 1 – 55(blue)
Wavelength (nm)	630 (red) 420 (blue)	633 (red)	415 (blue)	633 (red) 415 (blue)
Standard Dose (J/cm^2)	134.63 (red) 54 (blue)	(red)	48 (blue)	126 (red) 48 (blue)
Dose rate (mW/cm^2)	112 (red) 45 (blue)	105 (red)	40 (blue)	105 (red) 40 (blue)
Treatment Time (minutes)	20 (1200 sec)	20 (1200 sec)	20 (1200 sec)	20 (1200 sec)
Total Dose J/cm^2	134.4 (red) 54 (blue)	126 (red)	48 (blue)	126 (red) 48 (blue)

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b).

Instruction for use manual has been provided.

Deficiency: (b)(4) [redacted]

Response (s1): (b)(4) [redacted] This is adequate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00010

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Deficiency: (b)(4)

[redacted]

Response (s2):

(b)(4)

[redacted]

DJA k00011

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

VII. Sterilization/Shelf Life/Reuse

The *LIGHTWAVE™ Professional Delux LED System is provided non-sterile and is reusable.*

VIII. Biocompatibility: N/a

IX. Software

The user interface software allows the operator to access and control the device functions. The software was reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides an AI recommendation.

Response (s1): The firm's responses were reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides a succinct conclusion of SE.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety: N/a

XI. Performance Testing – Bench: N/a

XII. Performance Testing – Animal: N/a

XIII. Performance Testing – Clinical

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00012

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

XV. Deficiencies: see deficiencies as noted above

XVI. Contact History: see contact telephone conference calls as noted above

XVII. Recommendation: SE
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser instrument, surgical, powered
Regulatory Class: Class II
Product Code: GEX

Richard Paul Weiblinger, M.P.H. — Date: 1-4-2010

Neil Ogden, Branch Chief — Date: 1-4-2010

for

cc: RWeiblinger ODE/DSORD/GSDB
Gen. Surge Div.

Protecting and Promoting Public Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00013

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Felten, Richard P.

From: Felten, Richard P.
Sent: Thursday, December 24, 2009 9:07 AM
To: 'Michael Poling (mikep@mylightwave.com)'
Subject: K082586

Mr. Poling:

(b)(4) [redacted]

This can be sent to me by electronic mail since the document is in my office and once this is received I will move the application forward for final decision.

I do appreciate all you have done to respond to our concerns and I think the operator manual is in great shape.

I will try to also give you a call today depending on work schedule. We are only suppose to work half a day and since my day started at 7:00 I'm not sure how long I will be at work.

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic, and Restorative Devices
General Surgery Devices Branch

e-mail: Richard.Felten@fda.hhs.gov

phone: (301) 796-6392

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00014

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

January 4, 2010

Review of K082586/S3

Submitted by Lightwave Technologies

Reviewed by Richard P. Felten, DSORD, GSDB

Richard P. Felten

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00015

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

NOTICE: READ BEFORE OPERATING

The information supplied throughout this document should be used only as a guideline and does not constitute or replace medical advice. LIGHTWAVE™ Technologies is registered with the FDA.

- This manual must be kept for quick reference on use, cautions, maintenance and repair.
- Read this manual in its entirety before using the LIGHTWAVE™ system.
- Improper use of the LIGHTWAVE™ system can void the warranty. Please familiarize yourself with the limitations of the warranty and proper handling and storage of the system.
- The goggles included with the LIGHTWAVE™ unit are to be used at all times while operating any setting on the system. Due to the specific protection of the safety eye wear; they should never be used as protection with any other light or laser systems. Company issued replacement plastic goggles, stainless steel framed safety glasses, and disposable LED shields have all been shown to be effective. These varieties of eye protection are available for purchase through LIGHTWAVE™ Technologies.
- Should the panel ever come in direct contact with the skin for any reason, LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol swab to avoid cross contamination. NEVER clean the panel when the unit is powered "ON."
- WARNING: Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the LIGHTWAVE Professional Deluxe by children or incapacitated persons may be dangerous.

COPYRIGHT © 2002 LIGHTWAVE™ TECHNOLOGIES, LLC
No part of this instruction manual may be used to make derivative works based upon the original. No part of this information may be passed on, written down or used for commercial or private reproduction or any other purpose not specifically mentioned unless and until LIGHTWAVE™ Technologies LLC gives its written permission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00016

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18

Getting Started

LIGHTWAVE™ systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

Introduction

Thank you for choosing LIGHTWAVE™. This operating manual contains information on our LIGHTWAVE™ Professional light therapy system.

Below you will find a general overview of the LIGHTWAVE™ system as well as detailed sections throughout this guide providing you comprehensive knowledge of our systems' operation, and guidance on how to maintain it for years to come.

Please read the safety sections in their entirety before operating the system.

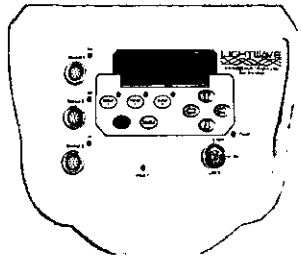
Again, we appreciate your confidence in LIGHTWAVE™ Technologies. Our customer care team welcomes any and all feedback with regard to our equipment. We can be reached by dialing toll-free at 866-999-6954.

System Overview

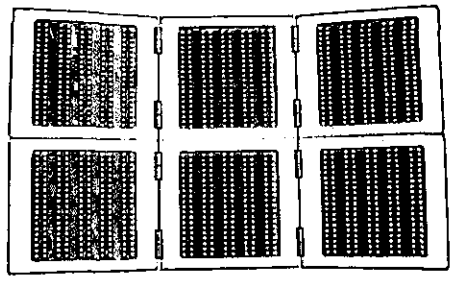
All LIGHTWAVE™ systems include a main unit and one accessory item.

Main Unit:

LIGHTWAVE's main unit features one touch button operation, a large LCD screen display, 3 accessory sockets, power supplies, operational software, and a locking on/off key switch.



Panels:



LIGHTWAVE's basic accessory item is the LED arm panel. It utilizes Red (630 nm), Infrared (880 nm) and Blue (420 nm) wavelengths. However, multiple wavelengths should ever be used simultaneously, use only one wavelength at a time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them. Each panel contains movable sections with independent hinges allowing it to adjust and form around the area being treated. This allows the panel to maintain a uniform distance from the treatment area which enables an even amount of light to be distributed. Please refer to *Positioning the Panel* for specific details on placing the panel over the treatment area.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00018

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

System Specs and Details

Output Intensity	Red 112 mW/cm2 Infrared 57mW/cm2 Blue 45mW/cm2
Output Wavelength	Red 630nm Infrared 880nm Blue 420 nm
Bandwidth	Red 25nm +/- 5nm Infrared 25nm +/- 5nm Blue 25nm +/-- 5nm
Light Source	SL SMT LED
Pulse	CW & Variable
Energy	1-168 joules
Coverage Area	Up to 1668 cm2
Electrical Supply	AC 110v or 220v
Weight	50lbs
Size	58 in (h) x 24 in (w)
Color	White, Grey and Black

Storage

The main unit is shipped inside a pink anti-static bag. This bag must be retained for future shipping needs should they arise. Failure to do so will result in additional material and handling charges.

Thoroughly clean the panel after each use and prior to storing. Please see *User Maintenance* for specific cleaning instructions.

When not in use, store the main unit and panel in a dust free environment to prolong the life of your system.

User Maintenance

Power off and unplug the LIGHTWAVE™ main unit prior to cleaning the system.

Any time the panel comes in direct contact with the patient's skin or that of the operator; LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol pad to avoid cross contamination. This is for your protection and the protection of your clients. Do not spray the system or accessories directly with an anti-bacterial solution but rather dampen a cloth with the solution and wipe down the panel and main unit. Never clean the panel when the unit is powered "ON."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00019

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Safety Warnings

Listed below are general safety instructions that apply to the operation of LIGHTWAVE™ equipment. This list includes many, but not all, of the safety instructions. Also refer to the safety guidelines and warnings shown in the rest of this manual and on the equipment.

Read this manual and all safety labels in their entirety before operating the equipment.

Do not operate the LIGHTWAVE™ around water as this can increase the risk for electrical shock. If liquid is spilled on the equipment, unplug the unit and call LIGHTWAVE™ immediately.

Do not operate the LIGHTWAVE's™ equipment around flammable liquids or gases. Doing so increases the danger of possible fire or explosion.

Do not restrict airflow to the panel or main unit. See *Positioning the Panel* for specific details on placing the panel over the treatment area. Make sure all air flow openings on the main unit are unobstructed and have proper ventilation.

If any wiring becomes exposed on the LED panel cable or power cord, do not operate equipment. Doing so can increase the risk for possible electrical shock

Use only the power source provided with the LIGHTWAVE equipment. Static electricity can cause harm to your system.

LIGHTWAVE's™ equipment should have its own dedicated wall socket or power strip. Do not power the equipment with a shared power strip.

Do not place foreign objects on or near the LIGHTWAVE™ equipment.

Never attempt to open the main unit or panel. Doing so puts the operator at risk for electrical shock. In addition, it voids all warranties and will cause permanent damage to your system.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, laying on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin.

Specific Safety Warnings: Eyes

The LIGHTWAVE™ equipment has been classified as a CLASS 2 device. The device is only capable of emitting low powered light at certain wavelengths making it incapable of causing eye injury within the normal aversion response to intense light.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00020

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The output of light produced during a treatment is greater than the recommended Maximum Permissible Exposure (MPE's) in the Blue and Infrared spectrum. It is absolutely imperative that the following guidelines are adhered to when operating the LIGHTWAVE™ equipment for the treatment of acne and for the temporary relief of minor muscle and joint pain.

The goggles provided with the LIGHTWAVE™ equipment are to be worn by the patient at all times when treatments are performed on or around the face and neck area. Goggles must be properly fitted over the retina and thoroughly disinfected with an anti-bacterial solution between treatments to avoid cross contamination.

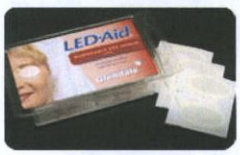
When treating your patient's face and neck area with blue or infrared light, it is essential to protect your client's eyes. In order to ensure proper protection and completely safeguard your client, apply the provided disposable LED eye aids under the standard LIGHTWAVE™ goggles. Optional metal block-out goggles are available for those clients who find the use of the disposable LED eye aids uncomfortable.

When treating other areas of the body (face and neck excluded), LIGHTWAVE™ recommends that the patient close their eyes for the entire duration of the treatment.

The operator does not directly view the light source for an extended period of time and therefore has a higher Maximum Permissible Exposure time. Due to the increased MPE time, the operator is not required to use protective eyewear. However, in order to properly protect the operator and limit their exposure time, IPL or Laser goggles are recommended.

Standard LIGHTWAVE supplied goggles

Optional LIGHTWAVE metal block-out goggles



LIGHTWAVE supplied disposable LED Aids

Contraindications

The safety of light therapy has been tested and no significant adverse reactions have been noted. However, using light therapy when treating patients with specific high-risk conditions has not been thoroughly established. Therefore, as a precaution LIGHTWAVE recommends not treating children or patients with the following conditions:

Acute or Cutaneous Porphyria, Lupus Erythematosus, Thyroid Problems, Photophobia Exogenous Eczema, Epilepsy & Seizures, Hypomelanism (albinism), Skin Cancer, Migraines Eye disease/retinal abnormalities, Diabetes, Pregnancy.

Specific to Acne Patients:
In rare cases cystic acne can increase rather than improve. Cystic acne patients should discontinue the light therapy treatment if they react unfavorably to the treatment. For any acne patient, if their condition worsens instead of improves, the solution is less light not more.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00021

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The following medications have been known to cause light sensitivity. If possible, medications listed below must be suspended for a minimum of one week before undergoing light therapy. If it is not possible to discontinue the use of a medication then your client must consult with their doctor before undergoing light therapy while continuing on the medication. It is further imperative that your client check with his/her doctor before discontinuing any prescribed medications.

Anti-Arrhythmic:	**Amiodarone** (Pacerone® Cordarone® Aratac®)
	Chlorpromazine (Thorazine®, Chloramead®, Chlordryprom®, Chlor® Promanyl®, Largactil®, Promapar®, Promosol®, Terpium®, Sonazine®)
Acne:	**Oral Isotretinoin** (Accutane®, Accure®, Aknenormin®, Amnesteem®, Ciscutan®, Claravis®, Isohexal®, Isotroin®, Oratane®, Sotret®, Roaccutane®)
	Topical Isotretinoin (Isotrex®, Isotrexin®)
Anti-Psychotic:	**Haloperidol** (Haldol®)
	Trifluoperazine (Stelazine®, Clnazine®, Novoflurazine®, Pentazine®, Solazine®, Terfluzine®, Triflurin®, Tripazine®)
Anti-Fungal:	**Griseofulvin** (Grifulvin®)
Antibiotics:	**Tetracycline** (Helidac®, Terra-Cortril®, Terramycin®, Sumycin®, Actisite®, Bristacycline®, Actisite®, Tetrex®, Doxycycline®, Ciprofloxacin®)
	Norfloxacin (Noroxin®, Quinabic®, Janacin®)
	Ofloxacin (floxin®, Oxaldin®, Tarivid®)
	Nalidixic acid (NegGam®, Wintomylon®)
	Ciprofloxacin (Cipro®, Ciproxin®, Ciprobay®)
	Minocycline (Minomycin®, Minocin®, Arestin®, Akamin®, Aknemin®, Solodyn®, Dynacin®, Sebomin®)
	Oxytetracycline
	Demeclocycline
	Lymecycline
Cancer:	**Methotrexate** (MTX®, Aminopterin®, Ledertrexate®)
Arthritis:	**Auranofin** (Ridaura®)-***If a patient is taking this medication; they are not a candidate for light therapy.***

The above drugs are currently the most common medications associated with photosensitivity and are by no means a complete list of all photosensitive medications. Herbs and over the counter medications such as psoralen and St. John's Wort can also cause sensitivity to light so it is important to stress to your client that they disclose any and all medications or herbs they are currently taking.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00022

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LIGHTWAVE Deluxe System

Intended 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00023

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Operating Instructions

Deluxe System Contents

1 – Control Unit
2 – Control Unit Keys
1 – 6ft Power Cord
1 - Stand with Casters and 2 Trays
1 - Arm with pole bracket
2 - 3 pc LED arm panels
1 - LED panel main cable
1- Power Surge Protector
1- Protective Eye Wear
1- User Manual and Protocol booklet

To Get Started

Image 1 - All LCU's come equipped with a 4-amp fuse to protect the unit from power surges. Always disconnect the power before accessing fuse.

Place the LIGHTWAVE™ Main Control Unit, (MCU) on a stable, flat surface or on the LIGHTWAVE™ stand. To turn on the LIGHTWAVE™ unit, connect the female end of the electrical power cord to the back of the unit. Plug the male connector into the **surge protector,** which needs to be connected to a standard 110v electrical outlet. Next, flip the On/Off switch to the **on (-)** position on the back of the MCU (See picture on the left).

Connecting LED Pads or Arm Assembly

Image 2 –Be sure the red dot is pointing up before inserting the connector into the socket port.

In order to connect the LED Panel assembly, the operator must first identify the RED dot on the collar of the connector tip. The red dot aligns pointing directly upwards when connecting the panel to the main control unit. After connecting the panel cord to the main unit, the cord needs to be connected to the arm panel. When connecting the arm cord to the arm panel, the red dot aligns pointing directly downwards instead of upwards as it did when you connected the cord to the base. After connecting the LED panel, the operator can turn ON the power switch if it has not already been done, which is located on the back of the MCU (LED panel may be plugged in with the power on or off). Upon starting, the unit will move through a number of initial screens that identify the machine's version of software and the model number. Then the control screen will indicate the present status of each socket.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00024

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Setting the Preset Programs

When the panel is connected to the MCU, the green indicator nearest to the corresponding socket button is illuminated indicating a good connection between the panel and the MCU (if you have correctly connected the panel and the green light is not lit, please consult Tech Support).

*Image 3-The **Main Control Display** pictured to the left shows that a main panel is plugged into socket one and the green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button that corresponds to the panel that has just been connected will bring up the **Socket Status Display** for that socket. The socket status display should appear as below.

*Image 4-The **Socket Status Display** pictured to the right shows that a main panel is plugged into socket one. The green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button again brings a blinking cursor to the program number. Using the up and down arrow keys allows the user to change from one program to the next. When the desired program is displayed, press enter, the blinking cursor will go away and the LIGHTWAVE™ unit is now ready to begin a treatment session. Pressing enter for a second time will start the treatment session. Please see *Performing Treatments* before initiating a treatment session.

Using the Machine "LOCK" Option

As an added safety feature, the operator can restrict the use of the machine from other users. By simply turning the key to the "OFF" position, the display will read "LOCKED" and no operations can be performed, completely disabling the LIGHTWAVE™ unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00025

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Using the "MENU"

The MENU can only be accessed from the **Main Control Display**. By pressing the RESET button, the user is sent to the Main Control Display screen. With the arrows blinking on either side of the word "MENU", press the ENTER button and the words similar to below will be shown. (Each one of the MENU options can be accessed by moving the blinking arrows with the up and down arrow keys.)

SET TIME AND DAY: Simply use the up and down arrow keys, along with ENTER to set the time and date.

ADD TREATMENTS: This function is for the units that are contracted on a pay per treatment program or other contract. Call Tech Support when using this menu.

RETURN: Returns the display to the Main Control Display.

Performing Treatments

Positioning the Panel

The proper placement of the panel is extremely important. If the panel is not correctly positioned over the treatment area, the dosage of light delivered can vary and affect the treatment outcome.

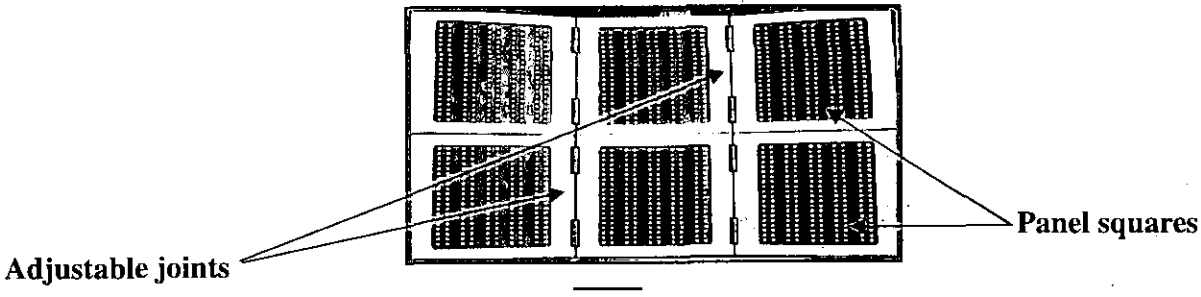
CAUTION: Never place the panel directly on open wounds, sunburns, or sensitive tissue. Restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin. If the panel is placed directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

NOTE: Never activate two separate wavelengths at the same time, only one wavelength should be used at one time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them.

Please follow these simple steps when positioning the panel:

1. Select the desired treatment area; keeping in mind the treatment area should not exceed the size of the panel. If the desired treatment area exceeds the panel size, additional treatments will need to be performed on the treatment area that extends beyond the panel boundaries.

2. The LED panel is designed with six adjustable joints and squares so that the panel will lay flat when treating surfaces such as the back or contour around a selected target area such as the face. Always adjust the panel at the joint.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

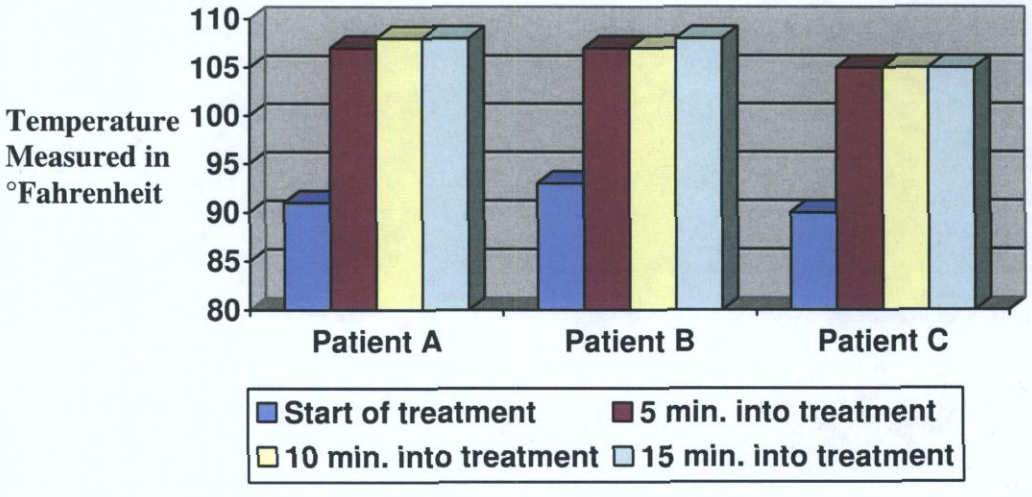
DJA x00026

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

3. When positioning the panel for a cosmetic treatment, evenly place the individual LED squares 1 inch from the target treatment area. When treating an uneven surface such as the face, the furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the panel at all times should remain within ½-1 inch from the surface of the target area. If the panel extends beyond the area of concern, the additional area will be exposed to light therapy. The further away the area is from the panel, the less photon energy the area will absorb. If you do not want to expose an area of skin to light, the excess skin can be covered with a thick cloth.

4. When positioning the panel for a treatment addressing a concern dealing with pain and discomfort within the body, the panel needs to increase the skin temperature to 104°F -113°F and maintain the elevated temperature throughout the duration of the treatment. In order to do so, you must evenly place the individual LED squares ½ inch from the target treatment area. When treating an uneven surface, the furthest extended point should be no more than ½ inch and no closer than ¼ inch from the LED panel. In order to ensure proper dose and temperature, the panel at all times should remain within ¼-½ inch from the surface of the target area.

AVERAGE SKIN TEMPERATURE READINGS FOR IR SETTING



As noted from the chart above, three patients' temperature readings were taken over a 15 minute treatment span. Based on the performance data, the IR setting on the panel is capable of raising and maintaining an elevated area temperature ranging from 104°F-109°F if the panel is correctly placed over the area of concern. Proper placement of the panel is essential in treating inflammation of the joints and muscle discomfort. If the panel is not within ½ of the target area, it is not capable of maintaining an elevated temperature throughout the treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00027

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Starting a Treatment

Once you have correctly set-up your system and properly positioned the LED panel, you are ready to start a treatment session. Before starting a treatment session, please read the *Protocol Usage Manual* so that you are familiar with the various treatment options.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Please read *Safety Warnings (pg. 5)* before starting a treatment.

Please follow the steps below to start a treatment:

1. Select the proper treatment setting corresponding to the desired treatment. Make sure the monitor exhibits the Socket Status Display screen (See image 4, pg. 10) by pressing the corresponding socket button to the matching treatment socket. Press the ENTER button. The screen will display a default setting for each program and is pre-set with the standard dose (See table 1, pg. 13.) To adjust the dose, use the left and right arrows to move the cursor to the number below the word DURATION (MIN). Once the number is highlighted, use the up and down arrows to decrease or increase the number which will adjust the time and dose according to the chart listed below.

2. Once the proper MIN have been selected press the ENTER button to activate the program. The Red indicator light should illuminate next to the socket that corresponds to the treatment socket that was just started. As long as the Red indicator is lit, this socket is active. Do not remove the arm panel until the treatment is complete. If a patient feels uncomfortable in any way proceed with the following - **Note: To Stop a Treatment, Press the "RESET" button in the Socket Status Display Screen. The custom setting will be saved until the main unit has been turned off. Custom Programs are not available on Pads.**

Dosage According to Panel Treatment Times				
Duration (min.)	**Infrared 880nm**	**Red 630nm**	**Blue 420nm**	
	57 mW/cm2	**112 mW/cm2**	**45mW/cm2**	
1	3.46 J/cm2	6.73 J/cm2	2.70 J/cm2	
5	17.28 J/cm2	33.66 J/cm2	13.50 J/cm2	
10	34.56 J/cm2	67.31 J/cm2	27.00 J/cm2	
15	51.84 J/cm2	100.97 J/cm2	40.50 J/cm2	
20	**69.12 J/cm2**	**134.63 J/cm2**	**54.00 J/cm2**	**Standard Dose**
25	86.40 J/cm2	168.29 J/cm2	67.50 J/cm2	* See warning below.

*Warning- There is no clinical data to substantiate the higher dose setting(s) at this time.

DJA x00028

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Clinical Applications

TREATING MILD TO MODERATE ACNE

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. However, only one wavelength should be used at a time. Never use blue and red simultaneously as this can reduce the treatment efficacy. The red light is capable of delivering a standard dose of 134.63 Joules/cm² in 20 minutes. The blue light is capable of delivering a standard dose of 54 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to Eye Safety Concerns for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to Placement of Panel (pg. 11) for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system; never using blue and red simultaneously as this can reduce the treatment efficacy. Please refer to Starting a Treatment (pg. 13). An initial eight treatment series starting with blue is recommended for this protocol over a 4 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week eight, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for MILD TO MODERATE ACNE (2 treatments per week with a minimum of 48 hours between treatment sessions. Never use red and blue together as this reduces efficacy.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take several bench mark photos.	✓			✓				✓
2	Cleanse skin with an anti-bacterial wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Blue Light session.	✓		✓		✓		✓	
4	Start 20 minute Red Light session.		✓		✓		✓		✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00029

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TREATING MODERATE INFLAMMATORY ACNE

THE LIGHTWAVE Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The blue light is capable of delivering a standard dose of 54 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial eight treatment series of blue is recommended for this protocol over a 4 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week eight, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for MODERATE INFLAMMATORY ACNE (2 treatments per week with a minimum of 48 hours between treatment sessions.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take several bench mark photos.	✓			✓				✓
2	Cleanse skin with an anti-bacterial wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Blue Light session.	✓	✓	✓	✓	✓	✓	✓	✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00030

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

TREATING PERIORBITAL WRINKLES

THE LIGHTWAVE Deluxe Red and Infrared light combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The red light is capable of delivering a standard dose of 134.63 Joules/cm² in 20 minutes. The infrared light is capable of delivering a standard dose of 69.12 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an exfoliating wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. A micro-exfoliating scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial seven treatment series is recommended for this protocol over a 5 week period. The client should receive an infrared LED light therapy treatment two times a week for the first week with at least 48 hours between treatment sessions. During week two, the client should receive two LED red light therapy treatments with at least 48 hours between treatment sessions. During weeks three, four, and five, the client should receive one infrared light therapy treatment each week. Before, during, and after photos should be taken at a minimum on week one, week four and week seven, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 7 LIGHTWAVE TREATMENT SESSIONS for PERIORBITAL WRINKLES **(1-2 treatments per week with a minimum of 48 hours between treatment sessions. Never use red and infrared together as this reduces efficacy.)**		**Session 1 (week 1)**	**Session 2 (week 1)**	**Session 3 (week 2)**	**Session 4 (week 2)**	**Session 5 (week 3)**	**Session 6 (week 4)**	**Session 7 (week 5)**
1	**Take several bench mark photos.**	✓			✓			✓
2	**Cleanse skin with an exfoliating wash.**	✓	✓	✓	✓	✓	✓	✓
3	**Start 20 minute Infrared Light session.**	✓	✓			✓	✓	✓
4	**Start 20 minute Red Light session.**			✓	✓			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00031

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

TREATING MINOR MUSCLE AND JOINT PAIN

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. The Infrared light is capable of delivering a standard dose of 69.12 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Caution should be taken not to place the panel directly on an open exposed cut or wound. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

When treating discomfort near the face and eye area, shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *placement of Panel (pg. 11)* for complete information on proper protection. If the area of concern is not near the face or eye area, the client still needs to close their eyes throughout the treatment session.

Step Three: Treatment Instructions

An initial minimum treatment series of four is recommended for this protocol over a two week period. The client should receive LED light therapy treatments two times a week with at least 24 hours between treatment sessions until the discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort the client actually experiences. If necessary, a client may continue treatment twice a week for up to a total of five weeks before discontinuing treatment.

TREATING SUPERFICIAL, BENIGN VASCULAR, AND PIGMENTED LESIONS

THE LIGHTWAVE Deluxe Red Light is intended to emit energy in the red spectrum for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions. The red light is capable of delivering a standard dose of 134.63 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Caution should be taken not to place the panel directly on an open exposed cut or wound. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light. Cleanse the entire target area with an exfoliating wash, removing all impurities and dead skin cells. For aged and/or

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00032

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment.

Step Two: Precautions

When treating vascular and pigmented lesions near the face and eye area, shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *placement of Panel (pg. 11)* for complete information on proper protection. If the area of concern is not near the face or eye area, the client still needs to close their eyes throughout the treatment session.

Step Three: Treatment Instructions

An initial minimum treatment series of eight is recommended for this protocol over a four week period. Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial eight treatment series is recommended for this protocol over a four week period. The client should receive a 20-minute red LED light therapy treatment two times a week for four weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week seven, documenting the client's progress. A follow-up appointment at week four is recommended. If necessary, a client may continue treatment twice a week for up to a total of five weeks before discontinuing treatment.

TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for VASCULAR & PIGMENTED LESIONS (2 treatments per week with a minimum of 48 hours between treatment sessions.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take several bench mark photos.	✓			✓			✓	
2	Cleanse skin with an exfoliating wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Red Light session.	✓	✓	✓	✓	✓	✓	✓	✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00033

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Troubleshooting

LIGHTWAVE's Basic Troubleshooting Guide

Problem	Possible Source	Mandatory Action
No Power	Power cable unplugged	Connect power cable to a working outlet
No Power	Surge Protector not on	Turn on surge protector
No Power	Power switch is set to "OFF" position	Turn switch to "ON" position
Display shows "LOCKED"	Key is set to "ON" position	Turn key to "OFF" position
System Shows "Panel READ ERROR"	Static build up	Unplug all devices from system and turn power off. Wait 2 minutes and turn on system without ay devices plugged in. Once system is completely on plug in devices one at a time.
"This device requires socket 1"	Device that requires socket 1 was plugged into socket 2 or 3.	Unplug device from socket 2 or 3 and plug into socket 1.
Program not turning on	Device not plugged into system correctly	Ensure that the device is plugged into the system and it is registered on the "Main Menu" screen.
Displays "Call Tech Support"		Call Tech support at 1-866-999-6954
Main Unit keeps asking for a confirmation #		Call Tech support for code

If the above actions do not rectify the problem or if an error occurs not listed on in the table, please call our help desk at 1-866-999-6954.

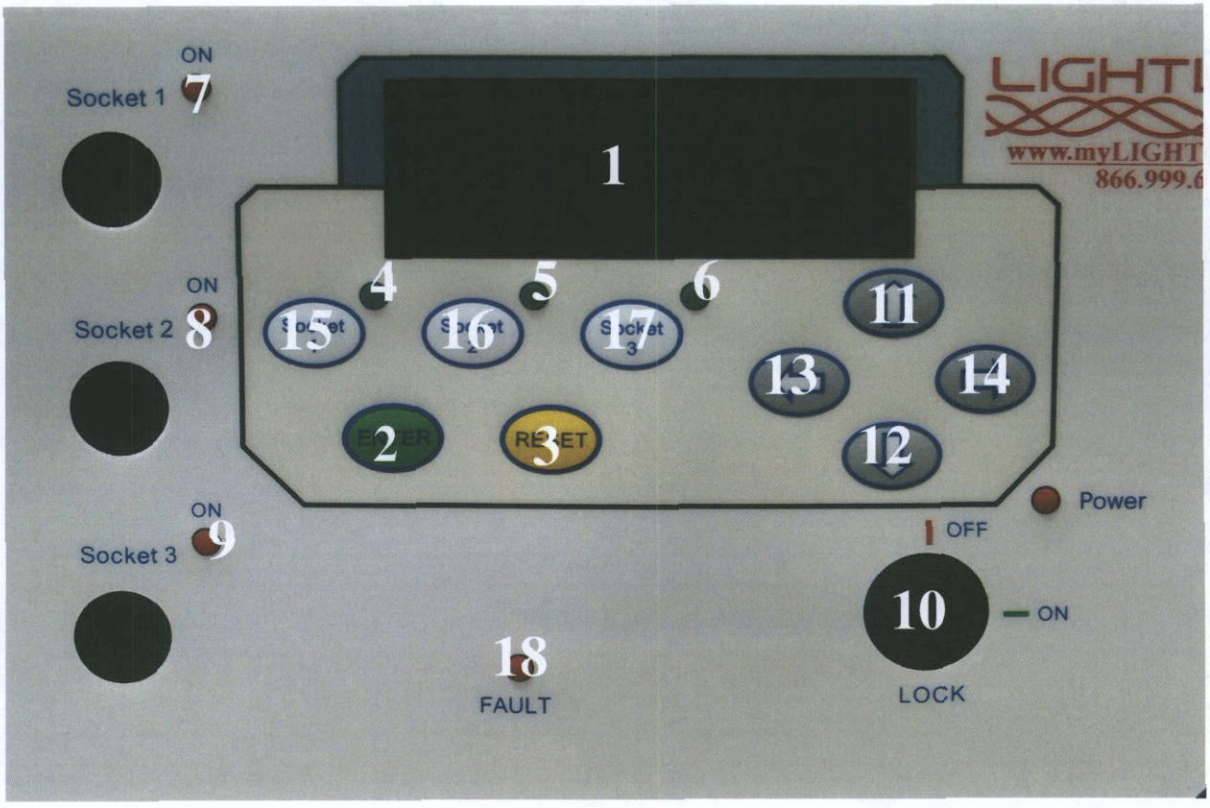
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00034

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Control Unit Membrane Index

MEMBRANE CONTROL SCREEN



1. LCD Display
2. Enter Button
3. Reset Button
4. Socket 1 Display Status Button
5. Socket 2 Display Status Button
6. Socket 3 Display Status Button
7. Socket 1 and Socket 1 Active Indicator
8. Socket 2 and Socket 2 Active Indicator
9. Socket 3 and Socket 3 Active Indicator
10. LOCK
11. Up Arrow
12. Down Arrow
13. Left Arrow
14. Right Arrow
15. Socket 1 Button
16. Socket 2 Button
17. Socket 3 Button
18. Fault Indicator

Please call us toll free at (866) 999 - 6954 Monday – Friday MST from 8:00 – 5:00 so we may address any questions or concerns you have with regard to this manual, protocols, usage, etc.

Once again, thank you for choosing LIGHTWAVE™.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00094

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name RICHARD WEIBLINGER

Subject: 510(k) Number K082586/S2

To: The Record

Please list CTS decision code _____

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use *only*?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

DJA x00095

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

Class II GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Neil R.P. Ogden GSDB 5/27/09

(Branch Chief) (Branch Code) (Date)

Final Review: _____

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00096

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: R. Weiblinger, Biologist
ODE/DGRND/GSDB
Subject: K082586s2
LIGHTWAVE™ Professional Delux LED System
To: Record

Review of K082586s2
Supplement

Submission date: 5/2609
Received date: 5/27/09
Review date: 5/29/09

Sponsor: *Lightwave Technologies LLC.*
ATTN: Maria Griffin or Mike Poling
c/o MDI Consultants, Inc.
55 Northern Blvd. Site 200
Great Neck, NY 11021
704-516-8197 or 516-482-9001 or
Mike poling Pres. 602-548-8808 or 602-738-4226 (cell)
Device: *LIGHTWAVE™ Professional Delux LED System*
Category: *Class II*
Product code: *GEX (21 CFR 878.4810)*

Introduction: The firm has submitted a premarket notification which is a marketing clearance request for the *LIGHTWAVE™ Professional Delux LED System.* The device is an LED diode panel array operating at 420 nm (visible blue), 630nm (visible red) for the treatment of acne and 830 nm (near infrared) for topical heating. The firm is now responding to FDA's request for additional information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00097

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Predicate Devices: The designated predicate devices are as described in the following table:

510 (k) Number	Manufacturer	Device
K043329	Photo Therapeutics, Ltd.	Omnilux Revive and Blue LED device for the treatment of acne
K043317	Photo Therapeutics, Ltd.	OmniLux Plus LED Device for topical heating
K043575	CareElectronics, Inc.	Dermillume Pro 1000 for the treatment of acne

Administrative Requirements

	Yes	No	N/
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

Proposed Indication: The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00098

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Labeling: Instruction for use manual has been provided.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00099

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Response (s2):

(b) (4)

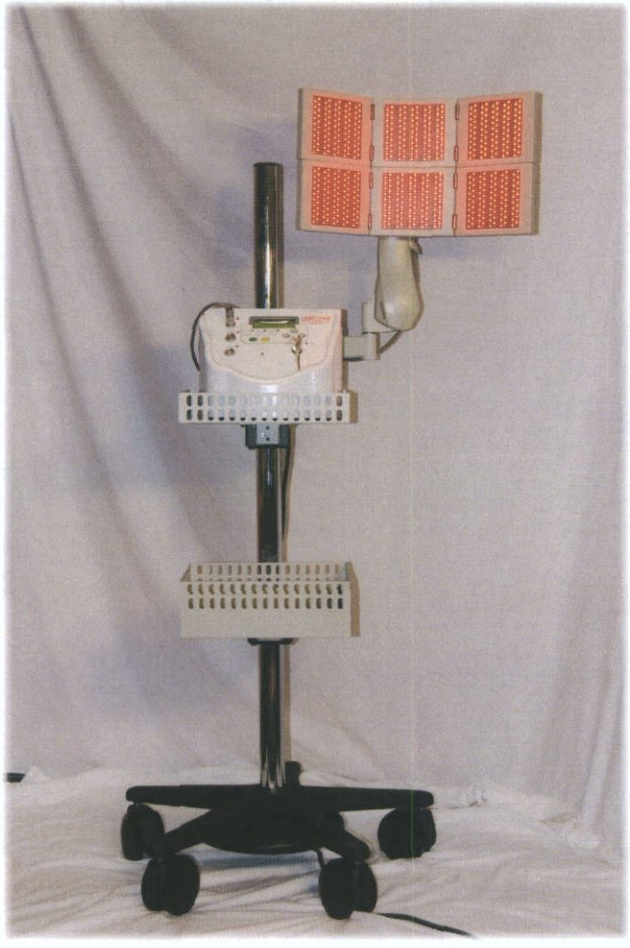
Device Description: The *LIGHTWAVE™ Professional Delux LED System consists of*

- *LED panels which can be configured to contain 1,2, or 3 rows of LED's (600, 1200, or 1800 LED's)*
- The customer has the option of purchasing the following sets of LED accessories; 1. Red and blue LED panels; 2. Red and infrared LED panels, or, 3. Red, blue and infrared LED panels.
- The system has 15 pre programmed software modules designed to address specific treatments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00100

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00101

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

A **comparison** of characteristics demonstrating SE features and technical specifications as compared to those of the predicate devices is provided below. The SE determination is based upon equivalence of the following characteristics: technical specifications (e.g. wavelength, and energy).

Device Characteristic	*LIGHTWAVE ™ Professional Delux LED System* K082586	CareElectronics, Inc. Dermillume Pro 1000 K043575	Photo Therapeutics, Ltd. Omnilux Revive Red and Blue LED device K043329	Photo Therapeutics, Ltd. Omnilux Plus LED device K043317
Indication	Acne Topical heating	Acne	acne	Topical Heating
Light Source	LED	LED	LED	LED
Dose Range (J/cm^2)	1 - 133.34 (red) 1 – 91.01(blue) 1 - 99.42 (near infrared)		1 – 150 (red) 1 – 55 (blue)	1 – 99.42 (near infrared)
Wavelength (nm)	630 (red) 420 (blue) 880 (near infrared)	660 (red) 414 (blue)	633 (red) 415 (blue)	830 (near infrared)
Standard Dose (J/cm^2)	126 (red) 48 (blue) 66 (near infrared)		126 (red) 48 (blue)	66 (near infrared)
Output Intensity (mW/cm^2)	1 - 82	10 (red) 20 (blue)	105 (red) 40 (blue)	55
Spot Size (coverage area cm^2)	Up to 1662	480	541.12	541.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00102

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

	Yes	No	N/
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	x		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

Sterilization: The *LIGHTWAVE™ Professional Delux LED System is provided non-sterile and is reusable.*

Software: The user interface software allows the operator to access and control the device functions. The software was reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides an AI recommendation.

Response (s1): The firm's responses were reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides a succinct conclusion of SE.

(b) (4)

[redacted]

Safety and Effectiveness Information: The firm has provided a 510(k) "summary", and a truthful and accurate statement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00103

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Recommended Regulatory Action: The firm's president; Mike Poling was contacted via telephone and was requested to provide the above mentioned information regarding revisions to their labeling, and directions for use. It is recommended that this submission should be placed on hold pending FDA's receipt of the above mentioned information.

Richard P. Weiblinger, M.P.H. *date*

Neil Ogden *5/22/07*
date

Chief, General Surgical Devices Branch, DGRD

I V Concur *I I Do Not Concur*

cc: RWeiblinger ODE/DGRD/GSDB
Gen. Surge Div.

Protecting and Promoting Public Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00129

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name RICHARD WEIBLINGER

Subject: 510(k) Number K082586/S1

To: The Record

Please list CTS decision code A.I.

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			—
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			—
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			—
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

ev. 7/2/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00130

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

Class II GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] GSD3 4/30/01

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00131

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: R. Weiblinger, Biologist
ODE/DGRND/GSDB
Subject: K082586s1
LIGHTWAVE™ Professional Delux LED System
To: Record

Review of K082586s1
Supplement

Submission date: 3/3/09
Received date: 3/4/09
Review date: 4/29/09

Sponsor: *Lightwave Technologies LLC.*
ATTN: Maria Griffin
c/o MDI Consultants, Inc.
55 Northern Blvd. Site 200
Great Neck, NY 11021
704-516-8197 or 516-482-9001 or Mike poling Pres. 602-548-8808
Device: *LIGHTWAVE™ Professional Delux LED System*
Category: *Class II*
Product code: *GEX (21 CFR 878.4810)*

Introduction: The firm has submitted a premarket notification which is a marketing clearance request for the *LIGHTWAVE™ Professional Delux LED System.* The device is an LED diode panel array operating at 420 nm (visible blue), 630nm (visible red) for the treatment of acne and 830 nm (near infrared) for topical heating. The firm is now responding to FDA's request for additional information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x001132

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Predicate Devices: The designated predicate devices are as described in the following table:

510 (k) Number	Manufacturer	Device
K043329	Photo Therapeutics, Ltd.	Omnilux Revive and Blue LED device for the treatment of acne
K043317	Photo Therapeutics, Ltd.	OmniLux Plus LED Device for topical heating
K043575	CareElectronics, Inc.	Dermillume Pro 1000 for the treatment of acne

Administrative Requirements

	Yes	No	N/
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

Proposed Indication: The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00133

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Labeling: Instruction for use manual has been provided.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00134

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Device Description: The *LIGHTWAVE™ Professional Delux LED System consists of*

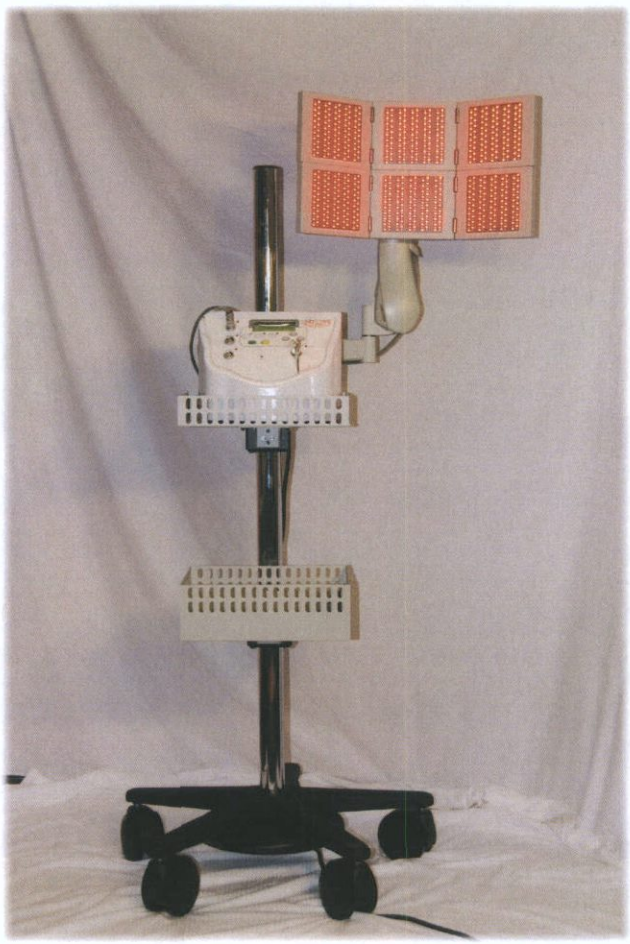
- *LED panels which can be configured to contain 1,2, or 3 rows of LED's (600, 1200, or 1800 LED's)*
- The customer has the option of purchasing the following sets of LED accessories; 1. Red and blue LED panels; 2. Red and infrared LED panels, or, 3. Red, blue and infrared LED panels.
- The system has 15 pre programmed software modules designed to address specific treatments

A **comparison** of characteristics demonstrating SE features and technical specifications as compared to those of the predicate devices is provided below. The SE determination is based upon equivalence of the following characteristics: technical specifications (e.g. wavelength, and energy).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x001135

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x001136

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Device Characteristic	*LIGHTWAVE ™ Professional Delux LED System* K082586	CareElectronics, Inc. Dermillume Pro 1000 K043575	Photo Therapeutics, Ltd. Omnilux Revive Red and Blue LED device K043329	Photo Therapeutics, Ltd. Omnilux Plus LED device K043317
Indication	Acne Topical heating	Acne	acne	Topical Heating
Light Source	LED	LED	LED	LED
Dose Range (J/cm^2)	1 - 133.34 (red) 1 – 91.01(blue) 1 - 99.42 (near infrared)		1 – 150 (red) 1 – 55 (blue)	1 – 99.42 (near infrared)
Wavelength (nm)	630 (red) 420 (blue) 880 (near infrared)	660 (red) 414 (blue)	633 (red) 415 (blue)	830 (near infrared)
Standard Dose (J/cm^2)	133.84 (red) 91.01 (blue) 99.42 (near infrared)		126 (red) 48 (blue)	66 (near infrared)
Output Intensity (mW/cm^2)	1 - 82	10 (red) 20 (blue)	105 (red) 40 (blue)	55
Spot Size (coverage area cm^2)	Up to 1662	480	541.12	541.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00137

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

	Yes	No	N/
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	x		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

Sterilization: The *LIGHTWAVE™ Professional Delux LED System is provided non-sterile and is reusable.*

Software: The user interface software allows the operator to access and control the device functions. The software was reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides an AI recommendation.

Response (s1): The firm's responses were reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides a succinct conclusion of SE.

(b) (4)

[redacted]

Safety and Effectiveness Information: The firm has provided a 510(k) "summary", and a truthful and accurate statement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x001138

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Recommended Regulatory Action: The firm was contacted via telephone and was requested to revise their labeling and directions for use. It is recommended that this submission should be placed on hold pending FDA's receipt of revised labeling.

Richard P. Weiblinger, M.P.H. *date*

Neil Ogden *date*
Chief, General Surgical Devices Branch, DGRD

/ / Concur */ / Do Not Concur*

cc: RWeiblinger ODE/DGRD/GSDB
Gen. Surge Div.

Protecting and Promoting Public Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x001139

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

MEMO OF

SOFTWARE REVIEW

of a MINOR Level Of Concern device

510(k): K082586/S001

DATE: 3/16/09

FROM: Joseph Jorgens III, Senior Biomedical and Software Engineer OSEL-DESE 301-796-2258

TO: Richard Weiblinger (RPW) ODE/DGRND/GSDB 240-276-3639

SUBJECT: Software review of the Lightwave Technologies's LED Array. Lightwave– 2222 W Parkside Lane, Suite 111, Phoenix, Az. Contact: Maria Griffin – MDI Consultants 55 Northern Blvd Suite 200, Great Neck NY. 602-548-8808.

Succinct Conclusion: S.E.

The information contained within this submission is sufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, this submission be considered substantially equivalent.

SUMMARY:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00140

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Software Controlled Aspects of the Device

The software controls all the functioning and timing of the system.

Software Review

1. **Level of Concern: Acceptable**
   The firm provided their level of concern and the supporting rationale. MINOR

2. **Software Description: Acceptable**
   In the Supplement, in Attachment 5, Section 4, entitled SRS, the firm provided an acceptable summary overview of the device features that are controlled by software, and a description of the intended operational environment.

3. **Device (including software) Hazard Analysis: Acceptable**
   In the Supplement, in Attachment 5, Sections 5 and 6, entitled Device Hazard Analysis, the firm provided an acceptable description of the hazards (including clinical hazards) presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control

4. **Software Requirements Specifications (SRS): Acceptable**
   In the Supplement, in Attachment 5, Section 4, entitled SRS, the firm provided an acceptable summary of the functional requirements from the Software Requirements Specification document

5. **Architecture Design Chart: NOT necessary for MINOR**

6. **Software Design Specification (SDS) : NOT necessary for MINOR**

7. **Traceability: Acceptable**
   In the Supplement, in Attachment 5, Section 10, entitled Traceability Matrix, the firm provided an acceptable traceability matrix, which provides traceability among identified hazards and mitigations, requirements, specifications, and verification and validation testing.

8. **Software Development Environment Description: NOT necessary for MINOR**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00141

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

9. **Verification and Validation Documentation: Acceptable**
In the Supplement, in Attachment 5, Section 10, entitled validation and verification documentation the firm provided an acceptable software functional test plan including pass/fail criteria and results.

10. **Revision Level History: Acceptable**
In Table 5.5 – 2 the firm provided an acceptable revision history log, which provides the history of software revisions generated during the course of product development.

11. **Unresolved Anomalies (Bugs or Defects) : NOT necessary for MINOR**

RECOMMENDATION: SUBSTANTIALLY EQUIVALENT

The firm has provided acceptable documentation demonstrating that they have developed the software for this device under an appropriate software development program; that they have performed a hazard analysis from both the patient's and user's standpoint, and addressed those hazards; and carried out an appropriate validation process. These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other way. It is recommended that from a software standpoint this submission be considered substantially equivalent.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00245

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name RICHARD WEIBLINGER

Subject: 510(k) Number K082586

To: The Record

Please list CTS decision code A.I.

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☑ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	—	
510(k) Summary /510(k) Statement	*Attach Summary*	—	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	—	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)		—	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			—
All Pediatric Patients age<=21			—
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00246

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Is this device subject to Section 522 Postmarket Surveillance? (*Postmarket Surveillance Guidance*, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

Class II GEX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Neil R. O'Hara GSPB 10/9/08

(Branch Chief) (Branch Code) (Date)

Final Review: _____

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00247

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: R. Weiblinger, Biologist
ODE/DGRND/GSDB
Subject: K082586
LIGHTWAVE™ Professional Delux LED System
To: Record

Review of K082586
Original

Submission date: 9/5/08
Received date: 9/8/08
Review date: 9/30/08

Sponsor: *Lightwave Technologies LLC.*
ATTN: Maria Griffin
c/o MDI Consultants, Inc.
55 Northern Blvd. Site 200
Great Neck, NY 11021
704-516-8197 or 516-482-9001 or Mike poling Pres. 602-548-8808
Device: *LIGHTWAVE™ Professional Delux LED System*
Category: *Class II*
Product code: *GEX (21 CFR 878.4810)*

Introduction: The firm has submitted a premarket notification which is a marketing clearance request for the *LIGHTWAVE™ Professional Delux LED System.* The device is an LED diode panel array operating at 420 nm (visible blue), 630nm (visible red) for the treatment of acne and 830 nm (near infrared) for topical heating.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00248

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Predicate Devices: The designated predicate devices are as described in the following table:

510 (k) Number	Manufacturer	Device
K043329	Photo Therapeutics, Ltd.	Omnilux Revive and Blue LED device for the treatment of acne
K043317	Photo Therapeutics, Ltd.	OmniLux Plus LED Device for topical heating
K043575	CareElectronics, Inc.	Dermillume Pro 1000 for the treatment of acne

Administrative Requirements

	Yes	No	N/
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

Proposed Indication: The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00249

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

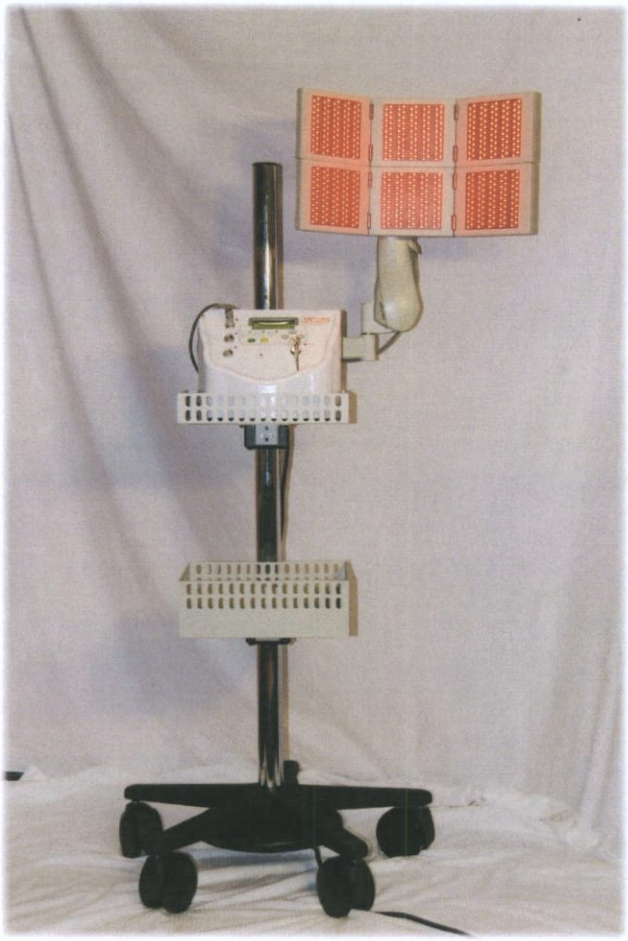
Labeling: Instruction for use manual has been provided.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00250

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00251

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Device Characteristic	*LIGHTWAVE ™ Professional Delux LED System* K082586	CareElectronics, Inc. Dermillume Pro 1000 K043575	Photo Therapeutics, Ltd. Omnilux Revive Red and Blue LED device K043329	Photo Therapeutics, Ltd. Omnilux Plus LED device K043317
Indication	Acne Topical heating	Acne	acne	Topical Heating
Light Source	LED	LED	LED	LED
Dose Range (J/cm^2)	1 - 133.34 (red) 1 – 91.01(blue) 1 - 99.42 (near infrared)		1 – 150 (red) 1 – 55 (blue)	1 – 99.42 (near infrared)
Wavelength (nm)	630 (red) 420 (blue) 880 (near infrared)	660 (red) 414 (blue)	633 (red) 415 (blue)	830 (near infrared)
Standard Dose (J/cm^2)	133.84 (red) 91.01 (blue) 99.42 (near infrared)		126 (red) 48 (blue)	66 (near infrared)
Output Intensity (mW/cm^2)	1 - 82	10 (red) 20 (blue)	105 (red) 40 (blue)	55
Spot Size (coverage area cm^2)	Up to 1662	480	541.12	541.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00252

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

	Yes	No	N/
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	x		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

Sterilization: The *LIGHTWAVE™ Professional Delux LED System is provided non-sterile and is reusable.*

Software: The user interface software allows the operator to access and control the device functions. The software was reviewed Joseph Jorgens CDRH/OSEL/DESE and a review memorandum is attached which provides a succinct conclusion of SE.

(b) (4)

[redacted]

Safety and Effectiveness Information: The firm has provided a 510(k) "summary", and a truthful and accurate statement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00253

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Recommended Regulatory Action: The above mentioned deficiencies were discussed with the firm (Mike Poling, president) during a telephone conference on 9/30/08. An e-mail (see attached) was forwarded to the firm which briefly outlines the additional information which was requested of the firm. It is recommended that this submission should be placed on hold and additional information (AI) should be requested.

Richard P. Weiblinger, M.P.H. *date*

Neil Ogden *date*
Chief, General Surgical Devices Branch, DGRD

/ / Concur

/ / Do Not Concur

cc: RWeiblinger ODE/DGRD/GSDB
Gen. Surge Div.

Protecting and Promoting Public Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DJA x00254

Weiblinger, Rick

From: Weiblinger, Rick
Sent: Tuesday, September 30, 2008 1:35 PM
To: mikep@mylightwave.com
Cc: 'Maria Griffin'
Subject: RE: Lightwave 510(k) Info K082586
Importance: High

Your submission is being placed on hold pending receipt of the additional information as discussed with you during our telephone conference today and as briefly outlined below.

(b)(4)

3. The following software additional information should be provided:

If you have questions concerning these additional information requests, please contact Joseph Jorgens III on 301-796-2588.

Prior to submitting the additional information, please familiarize yourself with the following software guidance documents:

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (http://www.fda.gov/cdrh/ode/guidance/337.pdf)
5/11/05

"Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices" (http://www.fda.gov/cdrh/ode/guidance/585.html)

"General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (issued 1/11/2002) (http://www.fda.gov/cdrh/comp/guidance/938.html)

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DJA x00255

For all the following information, please provide a table of contents with page numbers and tabbed sections, with each section repeating the question which is being addressed and clearly providing the answers to each of these additional information questions. If some of the information was provided in the original submission, please repeat that information in your response: do not just reference some previously submitted information.

(b)(4)

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DJA x00256

(b) (4) [redacted]

Richard P. Weiblinger, M.P.H.
U.S. Department of Health and Human Services
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
240-276-3600
richard.weiblinger@fda.hhs.gov

Protecting and Promoting Public Health

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at richard.weiblinger@fda.hhs.gov

---

From: Maria Griffin [mailto:Maria@mdiconsultants.com]
Sent: Tuesday, September 30, 2008 6:40 AM
To: Weiblinger, Rick
Cc: mikep@mylightwave.com
Subject: RE: Lightwave 510(k) Info

Dear Rick,

I received your voicemail late last night. I am traveling for the week and will not be available during work hours. I am checking my e-mails in the evening if you want to send me an e-mail requesting info or asking questions. If it is something urgent you can contact the alternate correspondent listed in the submission (Mike Poling cc'd on this e-mail).

Best regards,

Maria Griffin

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00257

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

MEMO OF

SOFTWARE REVIEW

of a MINOR Level Of Concern device

510(k): K082686

DATE: 9/19/08

FROM: Joseph Jorgens III, Senior Biomedical and Software Engineer OSEL-DESE 301-796-2258

TO: Richard Weiblinger (RPW) ODE/DGRND/GSDB 240-276-3639

SUBJECT: Software review of the Lightwave Technologies's LED Array. Lightwave – 2222 W Parkside Lane, Suite 111, Phoenix, Az. Contact: Maria Griffin – MDI Consultants 55 Northern Blvd Suite 200, Great Neck NY. 602-548-8808.

Succinct Conclusion: ADDITIONAL INFORMATION REQUIRED

The information provided in this submission is insufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, additional information be acquired in order to complete the review of this submission.

SUMMARY:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OSEL/DID at CDRH-OSMAIL@fda.hhs.gov or 301-796-5640

DJA x00258

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b) (4)

[redacted]

GENERAL CONCERNS:

(b) (4)

[redacted]

Software Controlled Aspects of the Device

The firm states that software controls many aspects of the device, but is not specific enough. Further information is requested infra.

(b) (4)

[redacted]

DJA x00259

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b) (4)

[redacted]

RECOMMENDATION: ADDITIONAL INFORMATION REQUIRED

For the reasons specified supra, it is recommended that the firm should be asked for the additional information before final approval is considered.

I will be happy to discuss these matters with the firm directly if that is more desirable. The following verbiage is offered as a possibility for inclusion in any oral or written correspondence with the firm.

If you have questions concerning these additional information requests, please contact Joseph Jorgens III on 301-796-2588.

Prior to submitting the additional information, please familiarize yourself with the following software guidance documents:

"Guidance for the *Content* of Premarket Submissions for Software Contained in Medical Devices"
(http://www.fda.gov/cdrh/ode/guidance/337.pdf)
5/11/05

"Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices"
(http://www.fda.gov/cdrh/ode/guidance/585.html)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00260

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

"General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (issued 1/11/2002) (http://www.fda.gov/cdrh/comp/guidance/938.html)

For all the following information, please provide a table of contents with page numbers and tabbed sections, with each section repeating the question which is being addressed and clearly providing the answers to each of these additional information questions. If some of the information was provided in the original submission, please repeat that information in your response: do not just reference some previously submitted information.

2. Software Description

You provided some software description, but it is inadequate.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00261

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00142

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

March 05, 2009

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

510k Number: K082586

Product: LIGHTWAVE PROFESSIONAL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00143

K082586/SI

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
1-866-999-6954 (TF)
(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

RETURN RECEIPT REQUESTED

March 3, 2009

FDA CDRH DMC
MAR - 4 2009
Received

Office of Device Evaluation
U. S. Food and Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

K-12

Reference: Additional Information Response for 510(k): K082586

Dear Sir/Madam:

Pursuant to the above-captioned 510(k) submissions, the following information is being submitted to Document Mail Center per the FDA letter dated September 30, 2008 from the reviewer, Richard P. Weiblinger, FDA requesting additional information.

We have prepared our responses in the order of the questions presented to us by the letter as follows:

Question 1:

Response 1:

Question 2:

Response 2:

We trust that the aforementioned responses will be satisfactory.

If you have any questions, or require additional information, please feel free to call me at (704) 843-1675 or (516) 482-9001 or e-mail me at maria@mdiconsultants.com.

Sincerely,

Maria Griffin /da

Maria F. Griffin
Official Correspondent for
Lightwave Technologies, LLC
Attachments

A complete list of Attachments is annexed hereto.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00144

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Question 1:

(b) (4)

[redacted]

Question 2:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00145

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Question 3:

The following software additional information should be provided:

(b) (4)

[redacted]

Question 4:

4. **Software Description**
You provided some software description, but it is inadequate.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at: CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00146

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

(b) (4)

[redacted]

Response 4:

Refer to Attachment 5 "Software Documentation" section 4.1.

Question 5:

5. Device (including software) Hazard Analysis

(b) (4)

[redacted]

Question 6:

6. Software Requirements Specifications (SRS)

You provided many System Requirements, but it is inadequate.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00147

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Question 7:

7. Traceability

(b) (4)

[redacted]

Question 8:

8. Verification and Validation Documentation

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00148

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

LIST OF ATTACHMENTS

Attachment 1	Updated Main Document
Attachment 2	Updated 510(k) Summary
Attachment 3	Comparison Chart K050216
Attachment 4	User Manual
Attachment 5	Software Documentation
Attachment 6	Performance Data
Attachment 7	Protocol Booklet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00149

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2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
1-866-999-6954 (TF)
(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

August 22, 2008

Office of Device Evaluation
U. S. Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, a pre-market notification is hereby made of the intention of **LIGHTWAVE Technologies LLC** to introduce into interstate commerce for commercial distribution a Laser Instrument, Surgical powered to be known as the **LIGHTWAVE Professional Deluxe**.

The following information is being submitted in conformance with 21 CFR Part 807.87, and the FDA Guidance Document entitled: "Information required in a Premarket Notification Submission", and "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices" as follows:

Section 1 – General Information

1. **Applicant:** **LIGHTWAVE Technologies LLC**
2222 W. Parkside Lane
Suite 111
Phoenix, AZ 85027
United States
Tel. 602 548 8808
Fax 602 548 8818

Registration No.: Not Assigned yet

2. **Contact Persons:** Ms. Maria F. Griffin
Official Correspondent for
LIGHTWAVE Technologies LLC
MDI Consultants, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00150

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55 Northern Blvd., Suite 200
Great Neck, NY 11021
TEL: (704) 516-8197 or (516) 482-9001
FAX: (516) 482-0186
EMAIL: Maria@mdiconsultants.com

Alternate Only:
Mike Poling
President
LIGHTWAVE Technologies LLC
2222 W. Parkside Lane
Suite 111
Phoenix, AZ 85027
United States
Tel. 602-548-8808
Fax 602-548-8818
EMAIL: mikep@myLIGHTWAVE.com

a. Trade/Proprietary Name Including Model Number of Device:

LIGHTWAVE Professional Deluxe

b. Common Name or Classification Name (21 CFR Part 807.87) of Device:

Common Name:	laser instrument, surgical powered
Regulation:	878.4810
Product Code:	GEX
Panel:	79

Common Name:	infrared lamp
Regulation:	21 CFR 890.550
Product Code:	ILY
Panel:	89

c. Address of Manufacturing Facility/Sterilization Sites:

This device is not sterilized.

Manufacturer:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00151

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(b)(4) [redacted]

d. Class in which Device has been placed:

Class II

e. Reason for Premarket Notification:

New Device/Introduction of a device that is substantially equivalent to a legally marketed device.

f. Name of Legally Marketed Device which We Claim Substantial Equivalence (Predicate Device) and 510(k) Number Under Which It Was Cleared

Photo Therapeutics Ltd. K030883, K030426, K043317, K050216

g. Compliance with Requirements of the Federal FD&C Act:

This device has been classified as Class II, 21 CFR Part 878.4810 and 890.5500.

Section 2 – Summary & Certification

a. 510(k) Summary or Certification:

Please refer to Exhibit #1 "510(k) Summary", which is our summary of safety and effectiveness information upon which an equivalence determination can be based, which can be released to the public.

b. Class III Certification and Summary:

We are not claiming substantial equivalence to a Class III device, and a Class III Certification and Summary is not included.

c. Kit Certification and Information:

This device is not a kit.

d. Truthful and Accuracy Statement:

Please refer to Exhibit 2 for the "Truthful and Accuracy Statement", which has been signed by a responsible person in our company.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00152

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Section 3 – Indications for Use

The LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the Red and Infrared spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles.

Please also refer to the "Indications for Use Statements", which are attached as Exhibit 3.

Section 4 – Description of Device

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 arm 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.

The LED accessories that are used with the base unit include: red, blue and infrared. The customer has a choice of purchasing the following sets of LED

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accessories: 1. red and blue LED panels, 2. red and infrared LED panels or 3. red, blue and infrared LED panels.

The table below illustrates the possible configurations:

Configuration	LED Panel			Main Unit		
	H (in)	W (in)	Area (in^2)	H (in)	W (in)	Area (in^2)
1 Row Panel	3.92	6.3	24.696	8	10	80
2 Row Panel	7.84	12.6	98.784	8	10	80
3 Row Panel	11.76	18.9	222.264	8	10	80

The unit has 9 pre-programmed software modules. All nine preset programs are designed to deliver enough power to stimulate a positive response from the body but do not deliver enough power to actually damage any of the surrounding tissues. The modules will not operate if the appropriate LED panels are not installed on the unit.

The following 9 programs have been designed to address the most common requested cosmetic treatments:

a. Wrinkles
b. Blemishes
c. Acute Discomfort
d. Chronic Discomfort
e. Red/Infrared Combo
f. Red/Blue Combo
g. Red Only
h. Infrared Only
i. Blue Only

All treatments are between 15-20 minutes in duration. A more detailed description of each treatment setting may be found in the "LIGHTWAVE Professional Deluxe User Manual" which has been included as EXHIBIT 5.

1. Is the device life supporting or life sustaining?

No

2. Is the device an implant?

No

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3. **Is the device sterile?**

   No

4. **Is the device single use or reusable?**

   Reusable

5. **Is the device for prescription use?**

   Yes

6. **Is the device for hospital, home or mobile use?**

   Mobile

7. **Does the device contain a drug or biological product as a component?**

   No

8. **Is the device a kit?**

   No

9. **Is the device software driven?**

   Yes

10. **Is the device electrically operated?**

    Yes

11. **Are there applicable voluntary standards for this device?**

    Yes

Section 5 – Comparison to the 510(k) Cleared Device

1. Spot Size Difference:

The slight increased spot size or coverage area allows provider/user/technician more surface area to be exposed when needed (provider dictated). This variation in size allows the treatment to be performed on individuals of various sizes. The increased spot size posses no significant concern for the safety or effectiveness of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00155

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2. Programs – Wave/Duration:

LIGHTWAVE's setting for the CW waveform is equivalent to the CW protocol of the predicate Omnilux Revive. The pulsed waveform, which varies based on user selection, is within the same parameters of the named predicates. Each of the predicates uses a similar range of waveform. All of LIGHTWAVE's preset parameters fall within the predicates and pose no significant concern for the safety or effectiveness of the device.

3. Treatment Protocols:

The treatment protocols for the LIGHTWAVE Professional Deluxe are similar or equivalent to the same characteristics of the compared legally marketed devices. The treatment time is within the same parameters as predicates.

A comparison chart has been created showing the similarities and differences of the subject device to the predicate devices.

Refer to Exhibit 4 for a copy of the "Comparison Chart".

Section 6 – Proposed Labeling for the Device
The following documents are included as proposed labeling for the device:

Exhibit # 5 LIGHTWAVE Professional Deluxe User Manual and Product Spec Sheet
Exhibit # 6 Predicate Device Promotional Material
Exhibit # 7 Photo of Subject Device

Section 7 - Electrical, Mechanical and Environmental/Performance Testing

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:

	Standard	Title
1	IEC 60601-1	**Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995**. (General)
2	IEC 60601-1-2:2001	**Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests**

Reference the following for supporting documentation:

Exhibit 8 "FDA 3654 Form for Standards"
Exhibit 9 "Bill of Materials"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00156

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Exhibit 11 "Electrical Safety/EMC Testing Documentation"
Exhibit 12 "Temperature Readings"
Exhibit 13 "Functional Test Procedure"

Conclusions Drawn from Tests and Analysis:

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 compared legally marketed devices.

Section 8 –Clinical Testing

Conclusions Drawn from Tests and Analysis:

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 compared legally marketed devices.

Clinical Performance Data:

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

Section 9 - Biocompatibility

We have assessed all of our patient contacting materials for biocompatibility requirements in accordance with the May 1, 1995 FDA Biocompatibility Guidance, the FDA-modified matrix of the "International Standard ISO-10993", "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", including the flow chart entitled "Biocompatibility Flow Chart for the Selection of Toxicity Tests of 510(k)'s.

Refer to Exhibit 9 "Bill of Materials" for a complete list of device components and materials. The device does not touch the patient.

Section 10 – Software

The software information for this submission was compiled in accordance with the following document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Please refer to Exhibit 10 for a copy of the "Software Requirements" document.

Additional Information: Quality Assurance and Manufacturing Controls:

LIGHTWAVE Technologies LLC operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (21 CFR Part 820), and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a formally established end controlled Quality Assurance Program. Devices are manufactured and assembled to established and controlled device master record requirements by formally trained and supervised personnel.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. Our intent to market this device is not considered public information and we have taken precautions to protect this confidentiality.

We would appreciate your reviewing this information at your earliest conveniences so that prompt reply to our request for clearance can be processed.

If you have any questions, or require additional information, please call me at (704) 516-8197 or (516) 482-9001. You can also reach me via e-mail at **Maria@mdiconsultants.com** or FAX me at (516)482-0186.

Sincerely,

LIGHTWAVE Technologies

Maria F. Griffin
Official Correspondent for
LIGHTWAVE Technologies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00158

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LIST OF EXHIBITS

EXHIBIT #1	510(k) Summary
EXHIBIT #2	Truthful and Accuracy Statement
EXHIBIT #3	Indications for Use Statement
EXHIBIT #4	Comparison Chart
EXHIBIT #5	Lightwave Professional Deluxe User Manual and Product Spec Sheet
EXHIBIT #6	Predicate Device Promotional Material
EXHIBIT #7	Photo of Subject Device
EXHIBIT #8	FDA 3654 Form for Standards
EXHIBIT #9	Bill of Materials
EXHIBIT #10	Software Requirements Document
EXHIBIT #11	Electrical Safety/EMC Testing Documentation
EXHIBIT #12	Temperature Readings
EXHIBIT #13	Functional Test Procedure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00159

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This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00160

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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 Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the Red and Infrared spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00161

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00162

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LED Comparison Chart & Technical Specifications				
Company	**LIGHTWAVE Technologies LLC**	**Photo Therapeutics, Ltd.**	**Photo Therapeutics Limited**	**SE or Different**
Device Name	**LIGHTWAVE Professional DELUXE**	**Omnilux Revive**	**Omnilux Plus**	
K Number	to be assigned	K050216	K050216	N/A
Regulation Number	878.4810	878.4810	890.5500	N/A
Product Code	GEX & ILY	GEX	ILY	SE
Light Source	LED (noncoherent) Multi diode	LED (noncoherent) Multi diode	LED (noncoherent) Multi diode	SE
Spectrum (wavelength)	630/880 nm	633 nm	830nm	SE
Delivery	Treatment Head - LED Array	Treatment Head - LED Array	Treatment Head - LED Array	SE
Output Intensity	1 ~ 82mW/cm^2	105mW/cm2	55mW/cm2	Different
Standard Dose	Red: 133.84 J/cm2 Infrared: 99.42 J/cm2	126 J/cm2	66 J/cm2	Different
Treatment Time	Up to 20 min	Up to 20 min	20 minutes	SE
Dose range (adjustable)	Red: 1-133.34 J/cm2 Infrared: 1-99.42 J/cm2	1-150 J/cm2	1-80 J/cm2	Different
Bandwidth	Red: 25nm +/-5nm Infrared 25nm +/-5nm	20 nm +/- 3 nm	30 nm +/- 5nm	SE
Wave Form	CW & Variable	CW	CW	SE
Target Population	Individuals Suffering from indicated dermatological conditions	Individuals Suffering from indicated dermatological conditions	Individuals Suffering from indicated dermatological conditions	SE
Location for use	Prescription use	Prescription use	Prescription use	SE
Spot Size (Coverage Area)	Up to 1662 cm2	541.12 cm2	541.2 cm2	Different
Intended use	The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and infrared region of the spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles.	The OmniLux Revive was cleared (K030426) for the use in dermatology for the treatment of superficial, benign vascular and pigmented lesions. The Omnilux Revive and Plus combination was cleared (K050216) for dermatological conditions, specifically indicated to treat periorbital wrinkles.	The Omnilux Plus was cleared (K043317) for topical heating for the intended purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain.The Omnilux Revive and Plus combination was cleared (K050216) for dermatological conditions, specifically indicated to treat periorbital wrinkles	SE
System Type	Table top/mobile workstation	Table top	Table top	SE
Size	58 in (H) x 24 in (W)	14 in (H) x 7 in (W)	14 in. (H) x 7 in. (W)	Different
Electrical Supply	AC 110VAC 220VAC 50/60 Hz	AC 110VAC 220VAC 50/60 Hz	AC 110VAC 220VAC 50/60 Hz	SE
Weight	84 lbs.	26 lbs	26lbs.	Different

DJA x00163

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NOTICE: READ BEFORE OPERATING

The information supplied throughout this document should be used only as a guideline and does not constitute or replace medical advice. LIGHTWAVE™ Technologies is registered with the FDA. The intended use of the LIGHTWAVE™ System is for the treatment of skin conditions which include cosmetic rejuvenation and acne.

- This manual must be kept for quick reference on use, cautions, maintenance and repair.
- Read this manual in its entirety before using the LIGHTWAVE™ system.
- Improper use of the LIGHTWAVE™ system can void the warranty. Please familiarize yourself with the limitations of the warranty and proper handling and storage of the system.
- The goggles included with the LIGHTWAVE™ unit are to be used at all times while operating any setting on the system. Due to the specific protection of the safety eye wear; they should never be used as protection with any other light or laser systems. Company issued replacement plastic goggles, stainless steel framed safety glasses, and disposable LED shields have all been shown to be effective. These varieties of eye protection are available for purchase through LIGHTWAVE™ Technologies.
- Should the panel ever come in direct contact with the skin for any reason, LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol swab to avoid cross contamination. NEVER clean the panel when the unit is powered "ON."
- WARNING: Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the LIGHTWAVE Professional Deluxe by children or incapacitated persons may be dangerous.

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No part of this instruction manual may be used to make derivative works based upon the original. No part of this information may be passed on, written down or used for commercial or private reproduction or any other purpose not specifically mentioned unless and until LIGHTWAVE™ Technologies LLC gives its written permission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00164

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Getting Started

LIGHTWAVE™ systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

Introduction

Thank you for choosing LIGHTWAVE™. This operating manual contains information on our LIGHTWAVE™ Professional light therapy system.

Below you will find a general overview of the LIGHTWAVE™ system as well as detailed sections throughout this guide providing you comprehensive knowledge of our systems' operation, and guidance on how to maintain it for years to come.

Please read the safety sections in their entirety before operating the system.

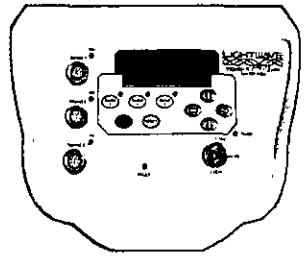
Again, we appreciate your confidence in LIGHTWAVE™ Technologies. Our customer care team welcomes any and all feedback with regard to our equipment. We can be reached by dialing toll-free at 866-999-6954.

System Overview

All LIGHTWAVE™ systems include a main unit and one accessory item.

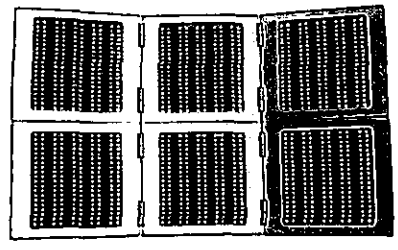
Main Unit:

LIGHTWAVE's main unit features one touch button operation, a large LCD screen display, 3 accessory sockets, power supplies, operational software, and a locking on/off key switch.



Panels:

LIGHTWAVE's basic accessory item is the LED arm panel. It utilizes Red (630 nm), Infrared (880 nm) and Blue (420 nm) wavelengths. Each panel contains movable sections with independent hinges allowing it to adjust and form around the area being treated. This allows the panel to maintain a uniform distance from the treatment area which enables an even amount of light to be distributed. Please refer to *Positioning the Panel* for specific details on placing the panel over the treatment area.



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System Specs and Details

Output Intensity	Red 112 mW/cm2 Infrared 82mW/cm2 Blue 86mW/cm2
Output Wavelength	Red 630nm Infrared 880nm Blue 420 nm
Bandwidth	Red 25nm +/- 5nm Infrared 25nm +/- 5nm Blue 25nm +/-- 5nm
Light Source	SL SMT LED
Pulse	CW & Variable
Energy	82 -248 joules
Coverage Area	Up to 1668 cm2
Electrical Supply	AC 110v or 220v
Weight	50lbs
Size	58 in (h) x 24 in (w)
Color	White, Grey and Black

Storage

The main unit is shipped inside a pink anti-static bag. This bag must be retained for future shipping needs should they arise. Failure to do so will result in additional material and handling charges.

Thoroughly clean the panel after each use and prior to storing. Please see *User Maintenance* for specific cleaning instructions.

When not in use, store the main unit and panel in a dust free environment to prolong the life of your system.

User Maintenance

Power off and unplug the LIGHTWAVE™ main unit prior to cleaning the system.

Any time the panel comes in direct contact with the patient's skin or that of the operator; LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol pad to avoid cross contamination. This is for your protection and the protection of your clients. Do not spray the system or accessories directly with an anti-bacterial solution but rather dampen a cloth with the solution and wipe down the panel and main unit. Never clean the panel when the unit is powered "ON."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Safety Warnings

Listed below are general safety instructions that apply to the operation of LIGHTWAVE™ equipment. This list includes many, but not all, of the safety instructions. Also refer to the safety guidelines and warnings shown in the rest of this manual and on the equipment.

Read this manual and all safety labels in their entirety before operating the equipment.

Do not operate the LIGHTWAVE™ around water as this can increase the risk for electrical shock. If liquid is spilled on the equipment, unplug the unit and call LIGHTWAVE™ immediately.

Do not operate the LIGHTWAVE's™ equipment around flammable liquids or gases. Doing so increases the danger of possible fire or explosion.

Do not restrict airflow to the panel or main unit. See *Positioning the Panel* for specific details on placing the panel over the treatment area. Make sure all air flow openings on the main unit are unobstructed and have proper ventilation.

If any wiring becomes exposed on the LED panel cable or power cord, do not operate equipment. Doing so can increase the risk for possible electrical shock

Use only the power source provided with the LIGHTWAVE equipment. Static electricity can cause harm to your system.

LIGHTWAVE's™ equipment should have its own dedicated wall socket or power strip. Do not power the equipment with a shared power strip.

Do not place foreign objects on or near the LIGHTWAVE™ equipment.

Never attempt to open the main unit or panel. Doing so puts the operator at risk for electrical shock. In addition, it voids all warranties and will cause permanent damage to your system.

WARNING: Use Carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, laying on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin.

Specific Safety Warnings: Eyes

The LIGHTWAVE™ equipment has been classified as a CLASS 2 device. This means that our device is only capable of emitting low powered light at certain wavelengths making it incapable of causing eye injury within the normal aversion response to intense light.

The FDA enforces a standard for light sources known as Maximum Permissible Exposure (MPE's). The output of light produced during a treatment is greater than the recommended MPE's in the Blue and Infrared spectrum. It is absolutely imperative that the following

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guidelines are adhered to when operating the LIGHTWAVE™ equipment for the treatment of acne and for the temporary relief of minor muscle and joint pain:

The goggles provided with the LIGHTWAVE™ equipment are to be worn by the patient at all times when treatments are performed on or around the face and neck area. Goggles must be properly fitted over the retina and thoroughly disinfected with an anti-bacterial solution between treatments to avoid cross contamination.

When treating your patient's face and neck area with blue or infrared light, it is essential to protect your client's eyes. In order to ensure proper protection and completely safeguard your client, apply the provided disposable LED eye aids under the standard LIGHTWAVE™ goggles. Optional metal block-out goggles are available for those clients who find the use of the disposable LED eye aids uncomfortable.

When treating other areas of the body (face and neck excluded), LIGHTWAVE™ recommends that the patient close their eyes for the entire duration of the treatment.

The operator does not directly view the light source for an extended period of time and therefore has a higher Maximum Permissible Exposure time. Due to the increased MPE time, the operator is not required to use protective eyewear. However, in order to properly protect the operator and limit their exposure time, IPL or Laser goggles are recommended.

Standard LIGHTWAVE supplied goggles

Optional LIGHTWAVE *metal block-out goggles*

LIGHTWAVE supplied *disposable LED Aids*

Contraindications

The safety of light therapy has been tested and no significant adverse reactions have been noted. However, using light therapy when treating patients with specific high-risk conditions has not been thoroughly established. Therefore, as a precaution LIGHTWAVE recommends not treating children or patients with the following conditions:

· Acute or Cutaneous Porphyria	· Lupus Erythematosus	· Thyroid Problems
· Photophobia	· Exogenous Eczema	·Epilepsy & Seizures
· Hypomelanism (albinism)	· Skin Cancer	· Migraines
· Eye disease/retinal abnormalities	· Diabetes	· Pregnancy

Specific to Acne Patients

In rare cases cystic acne can increase rather than improve. Cystic acne patients should discontinue the light therapy treatment if they react unfavorably to the treatment. For any acne patient, if their condition worsens instead of improves, the solution is less light not more. Please refer to the specific protocols outlined in the *Protocol Usage Manual.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following medications have been known to cause light sensitivity. If possible, medications listed below must be suspended for a minimum of one week before undergoing light therapy. If it is not possible to discontinue the use of a medication then your client must consult with their doctor before undergoing light therapy while continuing on the medication. It is further imperative that your client check with his/her doctor before discontinuing any prescribed medications.

Anti-Arrhythmic: **Amiodarone** (Pacerone® Cordarone® Aratac®)

Chlorpromazine (Thorazine®, Chloramead®, Chlordryprom®, Chlor® Promanyl®, Largactil®, Promapar®, Promosol®, Terpium®, Sonazine®)

Acne: **Oral Isotretinoin** (Accutane®, Accure®, Aknenormin®, Amnesteem®, Ciscutan®, Claravis®, Isohexal®, Isotroin®, Oratane®, Sotret®, Roaccutane®)

Topical Isotretinoin (Isotrex®, Isotrexin®)

Anti-Psychotic: **Haloperidol** (Haldol®)

Trifluoperazine (Stelazine®, Clnazine®, Novoflurazine®, Pentazine®, Solazine®, Terfluzine®, Triflurin®, Tripazine®)

Anti-Fungal: **Griseofulvin** (Grifulvin®)

Antibiotics: **Tetracycline** (Helidac®, Terra-Cortril®, Terramycin®, Sumycin®, Actisite®, Bristacycline®, Actisite®, Tetrex®, Doxycycline®, Ciprofloxacin®)

Norfloxacin (Noroxin®, Quinabic®, Janacin®)

Ofloxacin (floxin®, Oxaldin®, Tarivid®)

Nalidixic acid (NegGam®, Wintomylon®)

Ciprofloxacin (Cipro®, Ciproxin®, Ciprobay®)

Minocycline (Minomycin®, Minocin®, Arestin®, Akamin®, Aknemin®, Solodyn®, Dynacin®, Sebomin®)

Oxytetracycline

Demeclocycline

Lymecycline

Cancer: **Methotrexate** (MTX®, Aminopterin®, Ledertrexate®)

Arthritis: **Auranofin** (Ridaura®)-***If a patient is taking this medication, they are not a candidate for light therapy.***

The above drugs are currently the most common medications associated with photosensitivity and are by no means a complete list of all photosensitive medications. Herbs and over the counter medications such as psoralen and St. John's Wort can also cause sensitivity to light so it is important to stress to your client that they disclose any and all medications or herbs they are currently taking.

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Conditions Being Treated By LED Therapy Worldwide

General:

- Skin Rejuvenation
- Pre and Post Laser Care
- Cellulite
- Striae Scars
- Alopecia and Thinning Hair
- Hyper-pigmentation and Sun Spots

Injuries:

- Rotator Cuff Tears
- Carpal Tunnel Syndrome
- Lower Back Problems
- Tempero-Mandibular Joint Problems
- Ligament and Tendon Tears
- Contusions
- Tissue Strains and Sprains

Inflammatory:

- Tendonitis
- Bursitis
- Myositis
- Synovitis
- Plantar Fascitis
- Rheumatoid Arthritis

Degenerative:

- Osteoarthritis
- Degenerative Disc Disease
- Fibromialgia
- Chronic Leg Ulcers
- Muscular Skeletal Disease
- Neuromuscular Disease
- Injured Nerves & Bone Fractures
- Whiplash Injuries
- Frozen Shoulder

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Operating Instructions

Deluxe System Contents

1 – Control Unit
2 – Control Unit Keys
1 – 6ft Power Cord
1 - Stand with Casters and 2 Trays
1 - Arm with pole bracket
2 - 3 pc LED arm panels
1 - LED panel main cable
1- Power Surge Protector
1- Protective Eye Wear
1- User Manual and Protocol booklet

To Get Started

Image 1 - All LCU's come equipped with a 4-amp fuse to protect the unit from power surges. Always disconnect the power before accessing fuse.

Place the LIGHTWAVE™ Main Control Unit, (MCU) on a stable, flat surface or on the LIGHTWAVE™ stand. To turn on the LIGHTWAVE™ unit, connect the female end of the electrical power cord to the back of the unit. Plug the male connector into the **surge protector,** which needs to be connected to a standard 110v electrical outlet. Next, flip the On/Off switch to the **on (-)** position on the back of the MCU (See picture on the left).

Connecting LED Pads or Arm Assembly

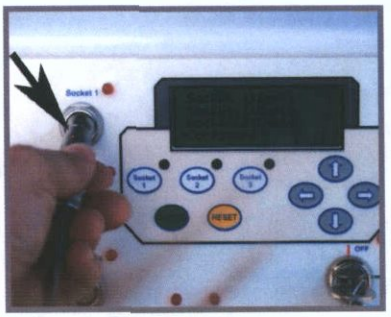

Image 2 –Be sure the red dot is pointing up before inserting the connector into the socket port.

In order to connect the LED Panel assembly, the operator must first identify the RED dot on the collar of the connector tip. The red dot aligns pointing directly upwards when connecting the panel to the main control unit. After connecting the panel cord to the main unit, the cord needs to be connected to the arm panel. When connecting the arm cord to the arm panel, the red dot aligns pointing directly downwards instead of upwards as it did when you connected the cord to the base. After connecting the LED panel, the operator can turn ON the power switch if it has not already been done, which is located on the back of the MCU (LED panel may be plugged in with the power on or off). Upon starting, the unit will move through a number of initial screens that identify the machine's version of software and the model number. Then the control screen will indicate the present status of each socket. R12DPA indicates the arm panel is connected.

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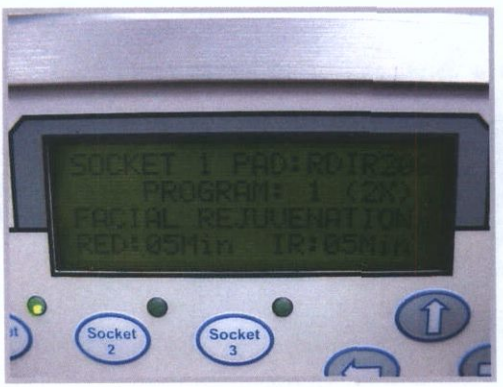
Setting the Preset Programs

When the panel is connected to the MCU, the green indicator nearest to the corresponding socket button is illuminated indicating a good connection between the panel and the MCU (if you have correctly connected the panel and the green light is not lit, please consult Tech Support).

*Image 3-The **Main Control Display** pictured to the left shows that a main panel is plugged into socket one and the green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button that corresponds to the panel that has just been connected will bring up the **Socket Status Display** for that socket. The socket status display should appear as below.

*Image 4-The **Socket Status Display** pictured to the right shows that a main panel is plugged into socket one. The green light next to the socket one button indicates that socket one is ready.*



Pressing the socket button again brings a blinking cursor to the program number. Using the up and down arrow keys allows the user to change from one program to the next. When the desired program is displayed, press enter, the blinking cursor will go away and the LIGHTWAVE™ unit is now ready to begin a treatment session. Pressing enter for a second time will start the treatment session. Please see *Performing Treatments* before initiating a treatment session.

Using the Machine "LOCK" Option

As an added safety feature, the operator can restrict the use of the machine from other users. By simply turning the key to the "OFF" position, the display will read "LOCKED" and no operations can be performed, completely disabling the LIGHTWAVE™ unit.

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Using the "MENU"

The MENU can only be accessed from the **Main Control Display**. By pressing the RESET button, the user is sent to the Main Control Display screen. With the arrows blinking on either side of the word "MENU", press the ENTER button and the words similar to below will be shown. (Each one of the MENU options can be accessed by moving the blinking arrows with the up and down arrow keys.)

SET TIME AND DAY: Simply use the up and down arrow keys, along with ENTER to set the time and date.

ADD TREATMENTS: This function is for the units that are contracted on a pay per treatment program or other contract. Call Tech Support when using this menu.

RETURN: Returns the display to the Main Control Display.

Performing Treatments

Positioning the Panel

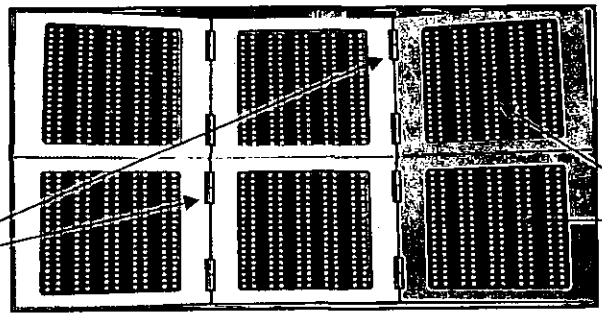
The positioning and proper placement of the panel is extremely important. If the panel is not correctly placed over the treatment area, the dosage of light delivered can vary and adversely affect the treatment outcome.

CAUTION: Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, sitting on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin. If you place the panel directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

Please follow these simple steps when positioning the panel:

1. Select the desired treatment area; keeping in mind the treatment area can not exceed the size of the panel as the treatment is localized to the treatment area only. If the desired treatment area exceeds the panel size, additional treatments will need to be performed on the treatment area that extends beyond the panel boundaries.

2. The LED panel is designed with six adjustable joints and squares so that the panel can lay flat when treating surfaces such as the back or contour around a selected target area such as the face. Make sure the panel is adjusted at the joint.



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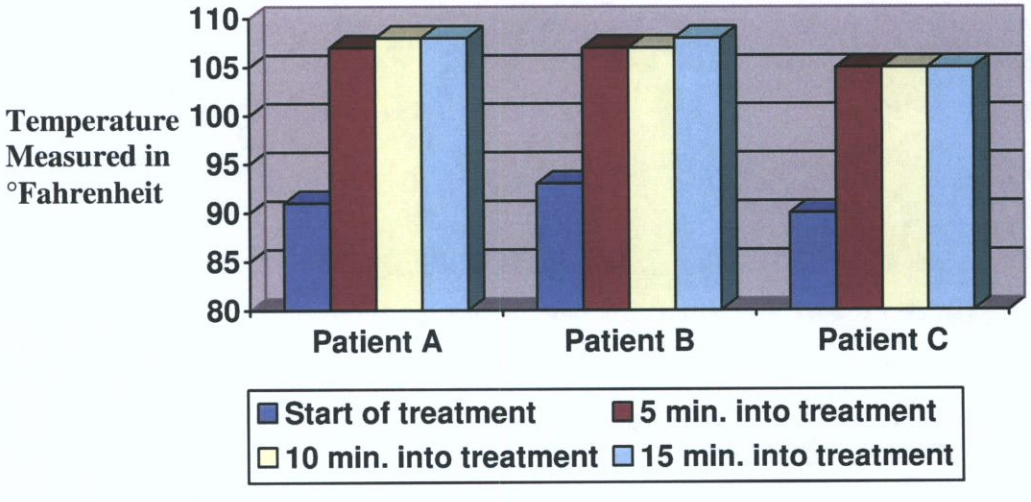
3. When positioning the panel for a cosmetic treatment, evenly place the individual LED squares 1 inch from the target treatment area. When treating an uneven surface such as the face, the furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the panel at all times should remain within ½-1 inch from the surface of the target area. If the panel extends beyond the area of concern, the additional area will be exposed to light therapy. The further away the area is from the panel, the less photon energy the area will absorb. If you do not want to expose an area of skin to light, the excess skin can be covered with a thick cloth.

4. When positioning the panel for a treatment addressing a concern dealing with pain and discomfort within the body, the panel needs to increase the skin temperature to 104°F -113°F and maintain the elevated temperature throughout the duration of the treatment. In order to do so, you must evenly place the individual LED squares ½ inch from the target treatment area. When treating an uneven surface, the furthest extended point should be no more than ½ inch and no closer than ¼ inch from the LED panel. In order to ensure proper dose and temperature, the panel at all times should remain within ¼-½ inch from the surface of the target area.

AVERAGE SKIN TEMPERATURE READINGS FOR IR SETTING



As noted from the chart above, three patients' temperature readings were taken over a 15 minute treatment span. Based on the performance data, the IR setting on the panel is capable of raising and maintaining an elevated area temperature ranging from 104°F-109°F if the panel is correctly placed over the area of concern. Proper placement of the panel is essential in treating inflammation of the joints and muscle discomfort. If the panel is not within ½ of the target area, it is not capable of maintaining an elevated temperature throughout the treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Starting Treatment

Once you have correctly set-up your system and properly positioned the LED panel, you are ready to start a treatment session. Before starting a treatment session, please read the *Protocol Usage Manual* so that you are familiar with the various treatment options.

WARNING: Use Carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Please read *Safety Warnings (pg. 5)* before starting a treatment.

Please follow the steps below to start a treatment:

1. Select the proper treatment program corresponding to the desired treatment area. *Please see Theory and Protocol Usage Overview (pg. 16) and the Protocol Usage Manual to select the proper program.* Make sure the monitor exhibits the Socket Status Display screen (See image 4, pg. 10) by pressing the corresponding socket button to the matching treatment socket.

2. Confirm the proper program is displayed, and then press ENTER. The Red indicator should illuminate next to the socket that corresponds to the socket that was just started. As long as the Red indicator is lit, this socket is active. Do not remove the arm panel until the treatment is complete. If a patient feels uncomfortable in any way proceed with the following - **Note: To Stop a Treatment, Press the "RESET" button in the Socket Status Display Screen.** For multiple treatments, simultaneously, repeat above procedures for other sockets.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting

LIGHTWAVE's Basic Troubleshooting Guide

Problem	Possible Source	Mandatory Action
No Power	Power cable unplugged	Connect power cable to a working outlet
No Power	Surge Protector not on	Turn on surge protector
No Power	Power switch is set to "OFF" position	Turn switch to "ON" position
Display shows "LOCKED"	Key is set to "ON" position	Turn key to "OFF" position
System Shows "Panel READ ERROR"	Static build up	Unplug all devices from system and turn power off. Wait 2 minutes and turn on system without ay devices plugged in. Once system is completely on plug in devices one at a time.
"This device requires socket 1"	Device that requires socket 1 was plugged into socket 2 or 3.	Unplug device from socket 2 or 3 and plug into socket 1.
Program not turning on	Device not plugged into system correctly	Ensure that the device is plugged into the system and it is registered on the "Main Menu" screen.
Displays "Call Tech Support"		Call Tech support at 1-866-999-6954
Main Unit keeps asking for a confirmation #		Call Tech support for code

If the above actions do not rectify the problem or if an error occurs not listed on in the table, please call our help desk at 1-866-999-6954.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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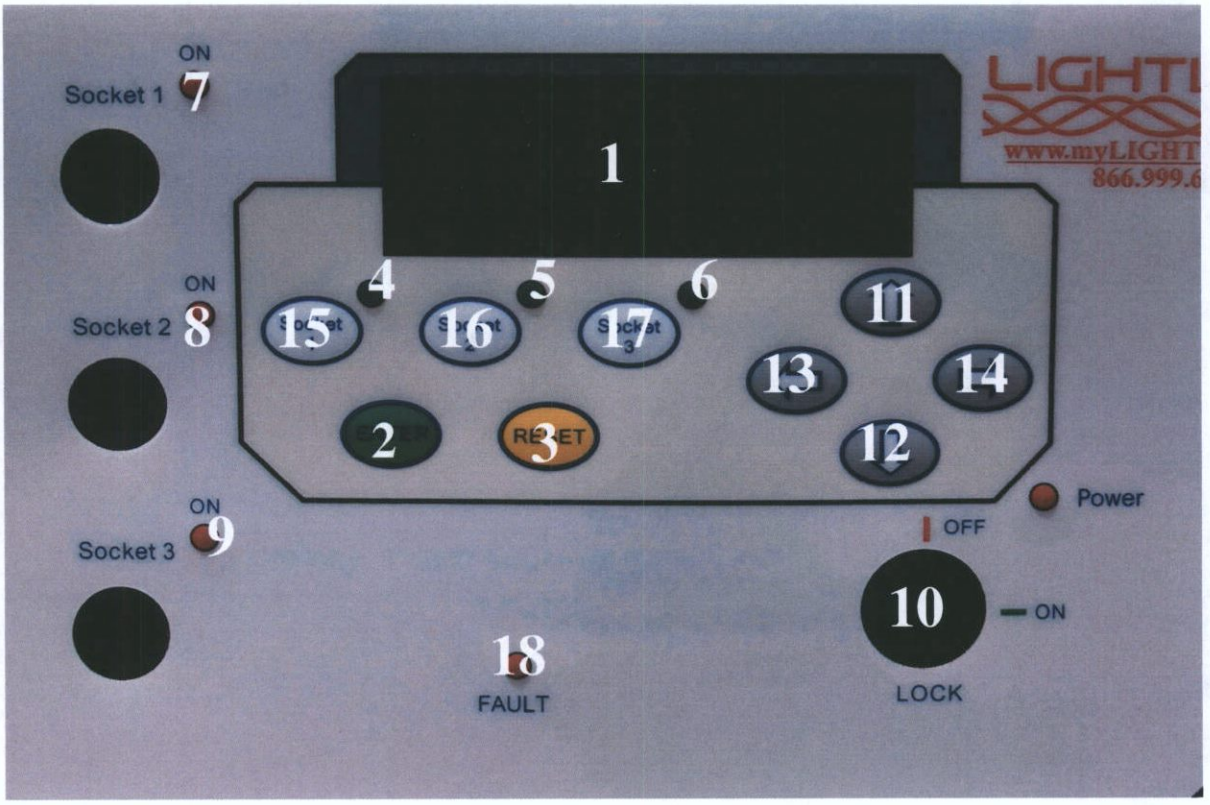
Control Unit Membrane Index

MEMBRANE CONTROL SCREEN



1. LCD Display
2. Enter Button
3. Reset Button
4. Socket 1 Display Status Button
5. Socket 2 Display Status Button
6. Socket 3 Display Status Button
7. Socket 1 and Socket 1 Active Indicator
8. Socket 2 and Socket 2 Active Indicator
9. Socket 3 and Socket 3 Active Indicator
10. LOCK
11. Up Arrow
12. Down Arrow
13. Left Arrow
14. Right Arrow
15. Socket 1 Button
16. Socket 2 Button
17. Socket 3 Button
18. Fault Indicator

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THERAPY, THEORY AND PROTOCOL INFO.

It is important to understand basic principles of light theory so that use of the LIGHTWAVE™ system can be maximized. Remember that each individual responds differently to light...some see noticeable effects much quicker than others. For example, we treated 29 year old twins for stretch marks and the one with a healthier lifestyle responded to treatments 3 sessions faster (10 total) than her sister (13 sessions). The following principles are generalities and specific results will vary from client to client.

A) Red light (630nm-640nm) penetrates human tissue more superficially, with approximately 80% of the energy being absorbed in the first 2cm. Red light energy has a significant effect on mitochondrial stimulation, which increases the production of ATP and in turn boosts fibroblast activity. This leads to an increase in cellular turn over and superficial circulation

B) Infrared (IR) wavelength (800nm - 900nm) energy penetrates deeper into tissue. Approximately 50% penetrates to 8cm and decreases to less than 1% at 20cm (NASA study). Infrared energy is known to heat tissue and its effects are well documented for therapeutic pain management. For cosmetic applications IR stimulates the NaK+ pump which increases cell membrane permeability; facilitating equilibrium of cellular pH, while increasing nutritional absorption and elimination of waste byproducts.

C) Blue (BL) wavelengths provide a more shallow penetration even with a high-intensity narrowband light source (405nm – 420nm). Most of the blue light energy is absorbed within the epidermis and dermis.

D) Red and infrared wavelengths affect tissue similarly with similar effects. However, each wavelength has a more intense effect on tissues of different densities and depth.

E) Red and Blue wavelengths provide intense light with a narrowband blue-light (415- to 425-nm) anti inflammatory emission and near-infrared (850- to 890-nm) emission inducing self-defense mechanisms that have been clinically proven effective for controlling bacteria and the release of sebum.

F) Biological effects such as an increase in collagen bundles and elastin fibers are increased when red and infrared energy is used in conjunction with each other. However, the two wavelengths should never be used simultaneously due to possible wavelength interference.

G) Tissues may be affected differently by pulsing the wavelengths between 10 Hz - 10,000 Hz. Slow pulses reduce nerve sensitivity by decreasing the production of Brinikin lucitrin necessary in the transmission of pain signals. Mid range pulses stimulate endorphin production while intense pulses stimulate mitosis and cellular repair. Each program incorporates multiple pulse frequencies designed for optimum tissue response for each indication.

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Theory & Protocol Usage Overview

Based on the previously mentioned principles, the following programs have been designed to address the most common requested cosmetic treatments. Remember all treatments are between 15-30 minutes in duration. Please refer to the *Protocol Usage Manual* for step by step treatment instructions. Below you will find a brief overview of each protocol.

1. Wrinkles – This pulsed 20-minute treatment is designed to re-hydrate the face, and increase collagen and elastin formation resulting in a reduction of fine lines and wrinkles. It aids in decreasing flaccidity, lifting sagging tissues and restoring skin tone and texture resulting in an overall improvement. Nine treatments are recommended. Maintenance once a month or as needed can prolong the youthful appearance.

2. Blemishes (Acne) - This intense continuous wave 20-minute setting is intended to normalize dry, oily, redness associated with problem skin. It is designed to increase blood circulation and bring more nutrients to the skin's surface to help to keep the skin from breaking down and achieving an overall improvement in skin tone and texture. This process may require ten or more treatments.

3. Acute Discomfort - This mid-pulsed 20-minute program is specifically designed to address inflammation associated with trauma and/or an allergic reaction that causes discomfort. It is usually used within 72 hours of any traumatic event including post-surgical interventions to reduce scarring and encourage normal tissue formation. The mid-pulses of light can be detected in the form of short flashes of light. Caution should be taken where superficial circulation has been compromised.

4. Chronic Discomfort – This pulsed 20-minute setting was developed with a focus on clients who experience persistent problems such as joint and muscle discomfort. Caution should be taken when treating clients with sensitive thin skin as this program induces a significant increase in tissue temperature.

5. Red/IR Combo - This 30-minute program has the same function as the Wrinkles Program (#1), but it delivers the treatment with more intensity as it uses continuous narrowband light instead of pulsed and is 30 minutes in duration. This will allow for treatment of clients with a thick dermal layer such as skin types 5 and 6.

6. Red/Blue Combo - P. acnes are often responsible for causing acne vulgaris when left untreated. This continuous wave 30-minute program is designed to repair damaged skin and significantly reduce any P. acnes bacteria that may be present and may lead to acne. First, the client is exposed to 15 minutes of blue light which enters the sebaceous glands and singlet oxygen is created. Singlet oxygen then in turn kills any bacteria that are present. Next, the client is exposed to 15 minutes of red light. This aids in the healing process of the skin by stimulating the production of pro-inflammatory cytokines, reducing any inflammation that may be present.

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7. Red Only – This continuous wave program is 15 minutes in duration and consists of red light only. Most of the energy from the red light is absorbed by the mitochondria, increasing the production of ATP. This protocol is designed to be used to treat uneven skin tone and texture, large pore size, redness, and edema on the skin's surface as well as superficial skin imperfections. It is often used following an ablative treatment such as IPL or laser resurfacing. Treatments should be administered twice weekly with at least 24 hours between treatment sessions until the skin no longer shows signs of redness or uneven skin tone/texture. The actual number of treatment sessions the client needs will depend greatly upon the extent of the patient's inflammation.

8. Blue only – This continuous wave program is 15 minutes in duration and consists of blue light only. The program is designed to kill the acne-causing bacteria, P. acnes, and is used to treat inflammatory acne vulgaris. Please refer to the *Protocol Usage Manual* for detailed information.

9. Infrared Only –This program is only 15 minutes in duration and consists of infrared (IR) light only. The 880 nm wavelength is intended to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

LIGHTWAVE™ AND ACNE

Acne Vulgaris is the most common of all skin disorders affecting nearly 85% of adolescents and young adults (usually between the ages of 15 to 24). Acne is a disease of pilosebaceous units in the skin. It is thought to be caused by the interplay of four factors: Sebaceous gland hyperplasia, excessive sebum production, hyperkeratinization of the hair follicle, and inflammation.

The main porphyrin produced by Propionibacterium acnes (P. acnes) is coproporphyrin III. Coproporphyrin III is a light sensitive substance with an absorption spectrum in the near UV and blue light spectrum. LIGHTWAVE's systems are equipped to illuminate these substances at the appropriate absorption spectrum to induce photoexcitation of bacterial porphyrins, singlet oxygen production, and ensuing bacterial destruction.

The optimal wavelength to achieve cell termination peaks at 415nm. LIGHTWAVE's systems deliver a wavelength of intense blue at 420nm therefore achieving this optimum level. We further combine red at 630nm to diminish the production of pro-inflammatory cytokines. The effects of combining intense light with a narrowband blue-light (415- to 425-nm) anti inflammatory emission and a near-infrared (850- to 890-nm) emission inducing

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self-defense mechanisms has been clinically proven effective for controlling bacteria and the release of sebum.

When choosing the most advantageous protocol for an acne patient, one must first exam the severity of their condition. LIGHTWAVE™ has uniquely designed protocols addressing acne in its most mild form including blackheads, whiteheads, and moderate inflammatory acne with pustules appearing at or near the surface of the skin. Please refer to the *Protocol Usage Manual* for specific protocol information.

Protocol Overview

Please refer to the *Protocol Usage Manual* for step by step directions and recommended protocols. In order to provide your clients with the best possible treatment outcomes, read the *Protocol Usage Manual* in its entirety and follow the steps and suggested treatments as outlined. You may also want to refer back to page six (6) of this manual and re-read the contraindications, both general and specific to acne.

Please call us toll free at (866) 999 - 6954 Monday – Friday MST from 8:00 – 5:00 so we may address any questions or concerns you have with regard to this manual, protocols, usage, etc.

Once again, thank you for your confidence in LIGHTWAVE™!

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Software Requirements Specification

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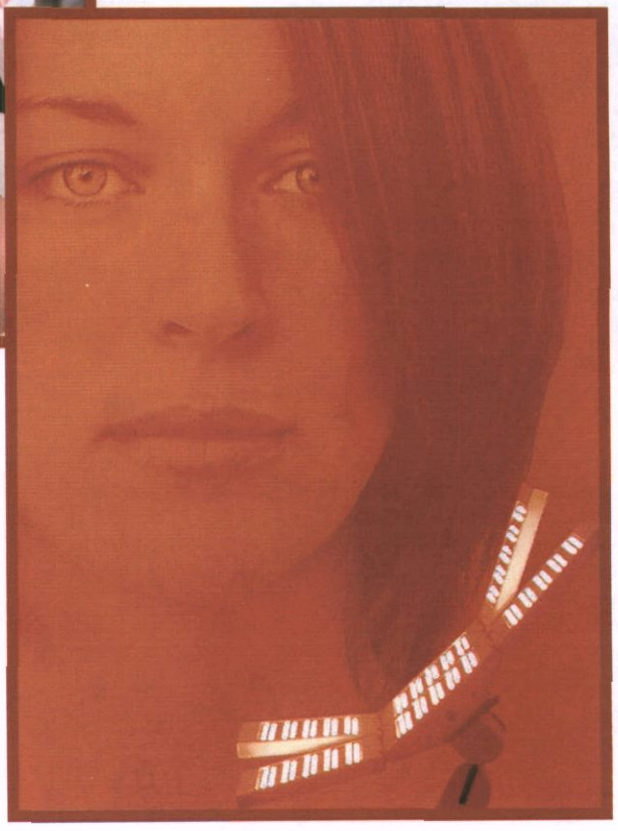
LIGHTWAVE

Protocol Usage Manual



LIGHTWAVE TECHNOLOGIES
PHOENIX, AZ
1-866-999-6954
WWW.MYLIGHTWAVE.COM

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PROTOCOL USAGE MANUAL

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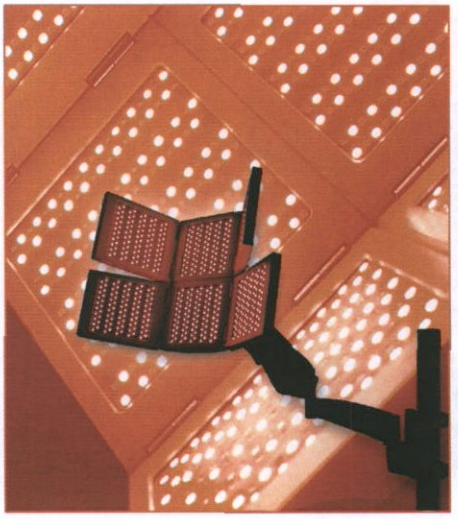
LIGHTWAVE systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

Introduction



The LIGHTWAVE Systems utilizes high-end Light Emitting Diodes (LED's) to distribute the specific wavelengths of light it radiates. This technology is commonly referred to as Photobiostimulation, Light Emitting Diode Therapy (LEDT) LLLT, or LED's. Clinically there have been recorded positive therapeutic effects for over the past 40 years documented by independent research and publications worldwide. The application of LED's to living tissue is non-invasive and provides a remarkable treatment alternative to traditional prescription medication and/or surgery.

While lasers and LED's have been used in medicine for years – for example, in eye surgeries and other delicate operations such as laser surgery – the scope of their full potential is just beginning to become widely known and accepted. Recent studies indicate that intense narrowband red and infrared light, which can penetrate below the skin, promotes the healing process and fuels over 20 different positive changes at a cellular level, including the increased production of collagen and elastin fibers. Current studies also point out the significant effects blue light can have on various topical skin conditions.

Instructional Overview

Light is electromagnetic radiation (photons), which means that **light = particles of energy**. Many terms are used when defining light. The terms most important pertaining to light therapy are **wavelength**, **frequency**, and **power** (watts). The **wavelength**, in short, is the color of the light measured in nanometers. The colors of light used in the LIGHTWAVE™ are red (630nm), infrared (880nm), and blue (417nm). The **frequency** of light is how many pulses per second the light is delivered in. The **power** of light is the strength or intensity of the light measured in watts or joules (i.e., 100 watt light bulb). Light therapy is very dependent upon these three characteristics of light.

As we go through our day, our bodies are bombarded by numerous wavelengths (colors) of light, all in different frequencies and different wattages.

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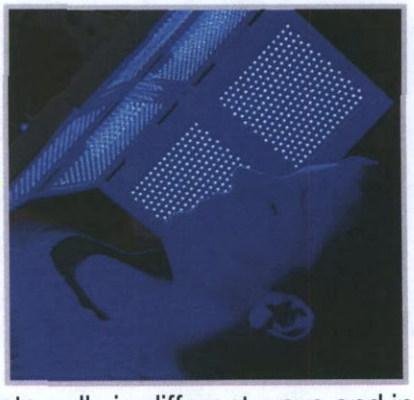
This light, which is produced mainly from the sun, affects our body's living tissue in many ways; so importantly - without it, we would die. Decades ago, it was found that red and infrared light had a very positive effect on cells in human and animal bodies', with different frequencies and powers affecting cells differently. The wavelengths of light used in the LIGHTWAVE™ systems are blue, red and infrared. The red and infrared are very close in wavelength; the range from red to infrared being 600 to 850 nm (nm=nanometers=unit of measure for the wavelength of light) respectively. The LIGHTWAVE systems use 630nm of red and 880nm of infrared. The blue light is found to be in the 400-480nm range with LIGHTWAVE systems using a wavelength of 420nm. The frequencies of light used in the system are from 0 Hz to 10 KHz (Hz=Hertz=unit of measure for the frequency of light). Zero Hz is commonly referred to as a continuous wave. The powers of light used in the LIGHTWAVE™ unit are from 60% to 100% of the total watts of each LIGHTWAVE™ panel.

How do wavelength, frequency, and power relate to light therapy?

When light (photons) is administered to tissue, it is painless; hence LIGHTWAVE™ treatments are painless. Studies have shown that LED light (photons) enters the tissue, stimulates the basic cell structure and function, and significantly increases cellular activity by increasing the production of adenosine triphosphate (ATP). Thus many conditions can be "jump started" and desired results can be experienced at a much more rapid rate.

Both red and infrared light are becoming well known for their undeniable restorative benefits, while blue light has been shown to be incredibly beneficial in reducing the presence of bacteria. When red, infrared and blue light are administered correctly, you can expect to see many positive changes; including an increase in collagen and elastin fiber synthesis, increased vascularity, a boost in phagocytosis, increased lymphatic system activity, a decrease in the presence of bacteria and a reduction in the excitability of nervous tissue. Blue and Red light address many surface or near surface imperfections and conditions, while infrared light penetrates much deeper. Certain frequencies of light stimulate cells in different ways and in general the power can be adjusted to give a more sensitive or more intense treatment.



Mass analysis of data from documented clinical studies has allowed LIGHTWAVE™ to use pre-programmed settings to help guide the user in achieving the best possible results. All preset programs are designed to deliver enough power to stimulate a positive response from the body but do not deliver enough power to actually damage any of the surrounding tissues. LIGHTWAVE™ therapy is a painless, safe and effective treatment with almost no known side-effects.

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The nine protocols that follow will help guide you through each program option. Before initiating a LIGHTWAVE session, please refer to ***Appendix 1: Eye Safety Concerns, Appendix 2: Contraindications for LIGHTWAVE Therapy, and Appendix 3: Placement of Panel.***

PROGRAM ONE - WRINKLES

Designed to help re-hydrate the face, and increase collagen and elastin formation reducing the appearance of fine lines and wrinkles. Reduces flaccidity, lifts sagging tissues and restores skin tone and structure to the face resulting in an overall noticeable skin improvement. For clients who have significant crow's feet or smoker's mouth, exfoliation is highly recommended prior to starting a light therapy session.

Note: Take all necessary before pictures of target area prior to starting session number one. If the photos are taken at the conclusion of the treatment, the skin can temporarily appear flushed and red in color.

Step One: Prepare the Skin

Cleanse the face and neck area with an Exfoliating Enzyme Wash or an Antibacterial cleanser, removing all impurities and dead skin cells. For aged and/or sun damaged skin additional exfoliation is recommended prior to starting the light therapy treatment. A Micro Exfoliating Scrub treatment, various chemical peels, and microdermabrasion are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the face and neck area. Evenly place the individual LED squares 1 inch from the target treatment area. The furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ½-1 inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

Finish the treatment by applying your topical skin care products. We suggest using one-two pumps of ABI's *Intense Antioxidant*, ABI's Firming Peptide Crème with Matrixyl 3000, followed by ABI's Sensible Sunblock with 40+ protection. It is important to always apply sunscreen and have the patient increase their water intake by 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial nine treatment series is recommended for this protocol over an 8-12 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 36 hours between treatment sessions. The 9th treatment session should occur on week 8-12 depending on the intensity and amount of exfoliation that occurred throughout the series of treatments. Less exfoliation will require the client to wait up to 12 weeks between the first session and session nine allowing the body's new healthy skin cells to reach the skin's surface. In order to maintain the achieved results, a single treatment session is recommended once every 6-8 weeks and as needed.

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PROGRAM TWO –PREVENTATIVE CARE

This intense continuous wave 20-minute program is commonly applied to young, healthy skin as a way to help slow down the signs of aging from appearing on the skin's exterior or on skin that shows redness or various areas of dry or oily patches. It is designed to increase blood circulation and bring more hydration and nutrients to the skin's surface to help keep the skin from breaking down. It also helps to normalize and balance out dry or oily skin, achieving an overall improvement in skin health.

Note: Take all necessary before pictures of target area prior to starting session number one. If the photos are taken at the conclusion of the treatment, the skin can temporarily appear flushed and red in color.

Step One: Prepare the Skin

Cleanse the face and neck area with an Exfoliating Enzyme Wash or an Antibacterial cleanser, removing all impurities and dead skin cells. For aged and/or sun damaged skin additional exfoliation is recommended prior to starting the light therapy treatment. A Micro Exfoliating Scrub treatment, various chemical peels, and microdermabrasion are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the face and neck area. Evenly place the individual LED squares 1 inch from the target treatment area. The furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ½-1 inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

Finish the treatment by applying your topical skin care products. We suggest using one-two pumps of ABI's Intense Antioxidant, followed by ABI's Sensible Sunblock. It is important to always apply sunscreen and have the patient increase their water intake by 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial nine treatment series is recommended for this protocol over an 8-12 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 36 hours between treatment sessions. The 9th treatment session should occur on week 8-12 depending on the intensity and amount of exfoliation that occurred throughout the series of treatments. Less exfoliation will require the client to wait up to 12 weeks between the first session and session nine allowing the body's new healthy skin cells to reach the skin's surface. In order to maintain the achieved results, a single treatment session is recommended once every 6-8 weeks and as needed. Maintenance treatments can inhibit breakouts from occurring especially during increased periods of stress.

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PROGRAM THREE - ACUTE DISCOMFORT

This program is specifically designed to address inflammation associated with trauma and discomfort. This 20 minute program is usually used within 72 hours of any traumatic event including post-surgical interventions to reducing swelling and encouraging normal tissue formation. This setting is also applied following a deep tissue massage to alleviate any discomfort from muscle and tissue manipulation. It has a mid-range pulse rate which can be detected by the human eye in the form of short flashes of light. This mid-range pulse stimulates an increase in endorphin release.

Step One: Prepare the Skin

Caution should be taken not to place the panel directly on wounds where circulation has been compromised or on an open exposed wound. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

When treating acute discomfort near the face and eye area, shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection. If the area of concern is not near the face or eye area, the client still needs to close their eyes throughout the treatment session.

Step Three: Treatment Instructions

Place the LED panel directly over the face and neck area. Evenly place the individual LED squares ½ inch from the target treatment area. The furthest extended point should be no more than ½ inch and no closer than a ¼ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ¼-½ inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

There is no required post care when treating patients who suffer from acute discomfort. However, it is always important to have the patient increase their water intake by a minimum of 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial minimum treatment series of four is recommended for this protocol over a two week period. The client should receive LED light therapy treatments two times a week with at least 24 hours between treatment sessions until the inflammation and discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort and the extent of inflammation the client actually experiences. If necessary, you may continue treatment twice a week for up to a total of five weeks before discontinuing treatment.

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PROGRAM FOUR - CHRONIC DISCOMFORT

This program is a pulsed 20 minute program which addresses the needs of clients with symptoms of persistent and chronic discomfort. Soft-tissue injuries found in the shoulders, knees, back and small joint areas as well as other prolonged and continuing ailments, typically see a decrease in discomfort approximately one - two hours after exposure. Caution should be taken when treating clients with sensitive, thin skin as this program induces a significant increase in tissue temperature.

Step One: Prepare the Skin

Caution should be taken not to place the panel directly on wounds where superficial circulation has been compromised or on open wounds. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

When treating chronic discomfort near the face and eye area, shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection. If the area of concern is not near the face or eye area, the client still needs to close their eyes throughout the treatment session.

Step Three: Treatment Instructions

For a specific area of discomfort, place the LED panel directly over the affected areas. For additional relaxation and tension reduction, place the panel at the base of the skull and run them parallel with the spine. Evenly place the individual LED squares ½ inch from the target treatment area. The furthest extended point should be no more than ½ inch and no closer than a ¼ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ¼-½ inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

There is no required post care when treating patients who suffer from chronic discomfort. However, it is always important to have the patient increase their water intake by a minimum of 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial minimum treatment series of six is recommended for this protocol over a two week period. The client should receive LED light therapy treatments three times a week with at least 24 hours between treatment sessions until the chronic discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort and the extent of inflammation the client actually experiences. If necessary, you may continue treatment for up to four weeks before discontinuing.

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PROGRAM FIVE – RED/IR COMBINATION

This 30-minute program has the same function as the Wrinkles Program (#1), but it delivers the treatment with more intensity as it uses continuous narrowband light instead of pulsed and is 30 minutes in duration. This will allow for treatment of clients with a thick dermal layer such as skin types 5 and 6.

Note: Take all necessary before pictures of target area prior to starting session number one. If the photos are taken at the conclusion of the treatment, the skin can temporarily appear flushed and red in color.

Step One: Prepare the Skin

Cleanse the face and neck area with an Exfoliating Enzyme Wash or an Antibacterial cleanser, removing all impurities and dead skin cells. For aged and/or sun damaged skin additional exfoliation is recommended prior to starting the light therapy treatment. A Micro Exfoliating Scrub treatment, various chemical peels, and microdermabrasion are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the face and neck area. Evenly place the individual LED squares 1 inch from the target treatment area. The furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ½-1 inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

Finish the treatment by applying your topical skin care products. We suggest using one-two pumps of ABI's Intense Antioxidant, ABI's Firming Peptide Crème with Matrixyl 3000, followed by ABI's Sensible Sunblock with 40+ protection. It is important to always apply sunscreen and have the patient increase their water intake by 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial seven treatment series is recommended for this protocol over an 8-12 week period. The client should receive LED light therapy treatments two times a week for the first 3 weeks with at least 36 hours between treatment sessions. The 7th treatment session should occur on week 8-12 depending on the intensity and amount of exfoliation that occurred throughout the series of treatments. Less exfoliation will require the client to wait up to 12 weeks between the first session and session seven allowing the body's new healthy skin cells to reach the skin's surface. In order to maintain the achieved results, a single treatment session is recommended once every 6-8 weeks and as needed.

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BACKGROUND INFORMATION FOR ACNE

Acne Vulgaris is the most common of all skin disorders affecting nearly 85% of adolescents and young adults (usually between the ages of 15 to 24). Acne is a disease of pilosebaceous units in the skin. It is thought to be caused by the interplay of four factors: Sebaceous gland hyperplasia, excessive sebum production, hyperkeratinization of the hair follicle, and inflammation.

The main porphyrin produced by Propionibacterium acnes (P. acnes) is coproporphyrin III. Coproporphyrin III is a light sensitive substance with an absorption spectrum in the near UV and blue light spectrum. LIGHTWAVE's systems are equipped to illuminate these substances at the appropriate absorption spectrum to induce photoexcitation of bacterial porphyrins, singlet oxygen production, ensuing in bacterial destruction.

The optimal wavelength to achieve cell termination peaks at 415nm. The 415nm wavelength simultaneously stimulates the leukocytes or white blood cells and the weakened bacteria become even more susceptible to destruction. LIGHTWAVE's system delivers a wavelength of intense blue narrowband light at 420nm, therefore achieving this optimum level. The effects of narrowband blue-light (415nm to 425nm) have been shown to be effective for controlling bacteria and treating mild to moderate acne vulgaris.

When choosing a protocol for a patient with problematic skin, a through analysis of the skin must be made to determine the cause of the skin condition. In some cases, topical skin care products that are comedogenic can cause the skin to become congested and inflamed. If it is determined that a client is using any comedogenic topical skin care products, they must refrain from using any of these products during the course of their LIGHTWAVE treatment series. LIGHTWAVE has designed protocols addressing both acne in its most mild form including blackheads and whiteheads; and moderate acne with inflamed pustules appearing at or near the surface of the skin. LIGHTWAVE is not designed to be used to treat severe acne including acne conglobata.

Caution: In some rare cases, inflammatory and cystic acne has increased rather than improved. Acne patients should discontinue the light therapy sessions if they react unfavorably to the treatment as scarring can occur if acne continues for a prolonged period of time.

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PROGRAM SIX–RED/BLUE LIGHT ONLY

P. acnes are often responsible for causing acne vulgaris when left untreated. This continuous wave 30-minute program is designed to repair damaged skin, reduce inflammation and significantly reduce any P. acnes bacteria that may be present and may lead to acne. First, the client is exposed to 15 minutes of blue light which enters the sebaceous glands and singlet oxygen is created. Singlet oxygen then in turn kills any bacteria that are present. Next, the client is exposed to 15 minutes of red light. This aids in the healing process of the skin by stimulating the production of pro-inflammatory cytokines, reducing any inflammation that may be present.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Evenly place the individual LED squares 1 inch from the treatment area. The furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ½-1 inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

Finish the treatment by applying your topical skin care products. We suggest wetting a cleansing cloth with ABI's Corrective Anti-Acne Mist and swabbing the target area. Then apply one or two pumps of ABI's Corrective Anti-Acne Treatment Gel, followed by ABI's Sensible Sunblock. It is important to always apply sunscreen and have the patient increase their water intake by 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial nine treatment series is recommended for this protocol over an 8 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 36 hours between treatment sessions. The 9th treatment session should occur on week 8. Before, during, and after photos should be taken at a minimum on week one, week four (which is when the majority of clients see the largest and most significant improvement in their skin) and week eight, documenting the client's progress.

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PROGRAM SEVEN – RED LIGHT ONLY

This program is only 15 minutes in duration and consists of red light only. The 630 nm wavelength stimulates the mitochondria and causes superficial circulation. Approximately 80% of the energy is absorbed in the first 2cm and decreases to less than 1% at 8cm. This protocol is designed to be used to treat redness, inflammation and issues on the surface of the skin.

Step One: Prepare the Skin

If possible, cleanse the treatment area with ABI's Exfoliating Enzyme Wash or ABI's Antibacterial cleanser, removing all impurities and dead skin cells. This will allow for proper light penetration in the target area. Caution should be taken not to place the panel directly on wounds where superficial circulation has been compromised or on open wounds. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

Shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Evenly place the individual LED squares 1 inch from the treatment area. The furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ½-1 inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

Finish the treatment by applying your topical skin care products. If you are treating redness and surface skin conditions, it highly recommend that you follow-up any treatment by applying one or two pumps of ABI's Hyaluronic Acid Peptide Gel followed by and ABI's Sensible Sunblock with 40+ protection to the target area. It is important to always apply sunscreen and have the patient increase their water intake by 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial minimum treatment series of four is recommended for this protocol over a two week period. The client should receive LED light therapy treatments two times a week with at least 24 hours between treatment sessions until the inflammation and discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort and the extent of inflammation the client actually experiences. If necessary, you may continue treatment twice a week for up to a total of three weeks before discontinuing treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00234

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PROGRAM EIGHT – BLUE LIGHT ONLY

This continuous wave program is 15 minutes in duration and consists of blue light only. The program is designed to kill the acne-causing bacteria, P. acnes, and is used to treat acne vulgaris. The client is exposed to 15 minutes of high-intensity narrowband blue light which enters the sebaceous glands and singlet oxygen is created. Singlet oxygen then in turn kills any bacteria that are present.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. It is important to use a topical cleanser that is non-comedogenic when working with acne skin. Additional exfoliation is not recommended prior to starting the light therapy treatment on skin with active acne as it can dry out and irritate the skin and in some cases may make the breakout worse.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Evenly place the individual LED squares 1 inch from the treatment area. The furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the complete panel at all times should remain within ½-1 inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

Finish the treatment by applying your topical skin care products. We suggest wetting a cleansing cloth with ABI's Corrective Anti-Acne Mist and swabbing the target area. Then apply one or two pumps of ABI's Corrective Anti-Acne Treatment Gel, followed by ABI's Sensible Sunblock. It is important to always apply sunscreen and have the patient increase their water intake by 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial nine treatment series is recommended for this protocol over an 8 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 36 hours between treatment sessions. The 9th treatment session should occur on week 8. Before, during, and after photos should be taken at a minimum on week one, week four (which is when the majority of clients see the largest and most significant improvement in their skin) and week eight, documenting the client's progress.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00235

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

PROGRAM NINE - INFRARED LIGHT ONLY

This program is only 15 minutes in duration and consists of infrared (IR) light only. The 880 nm wavelength is intended to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied.

Step One: Prepare the Skin

If possible, cleanse the treatment area with ABI's Exfoliating Enzyme Wash or ABI's Antibacterial cleanser, removing all impurities and dead skin cells. This will allow for proper light penetration in the target area. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

Shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Appendix 1: Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Evenly place the individual LED squares ½ inch from the treatment area. The furthest extended point ½ inch and no closer than a ¼ inch from the LED panel. In order to ensure proper dose and temperature elevation, the complete panel at all times should remain within ½ inch from the surface of the target area. Please refer to *Appendix 3: Placement of Panel* for more detailed information on positioning the panel. Once the Panel has been properly placed, follow the directions in the *Operator Manual* to initiate the program.

Step Four: Post Care

There is no required post care when treating patients who suffer from discomfort. However, it is always important to have the patient increase their water intake by a minimum of 8 oz. following a light therapy treatment.

NUMBER OF SUGGESTED TREATMENTS: An initial minimum treatment series of six is recommended for this protocol over a two week period. The client should receive LED light therapy treatments three times a week with at least 24 hours between treatment sessions until the stiffness and discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort and the extent of inflammation the client actually experiences. If necessary, you may continue treatment for up to three times a week for four weeks before discontinuing. When treating joint inflammation, a single continued weekly treatment may be necessary to keep the inflammation under control.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 1- Eye Safety Concerns

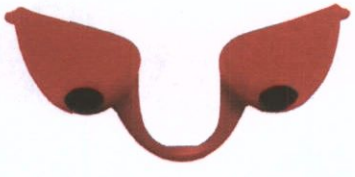
The FDA enforces a standard for light sources known as Maximum Permissible Exposure (MPE's). The output of light produced during a treatment is greater than the recommended MPE's in the Blue and Infrared spectrum. It is absolutely imperative that the following guidelines are adhered to when operating the LIGHTWAVE™ equipment for the treatment of acne and for the temporary relief of minor muscle and joint pain:

The goggles provided with the LIGHTWAVE™ equipment are to be worn by the patient at all times when treatments are performed on or around the face and neck area. Goggles must be properly fitted over the retina and thoroughly disinfected with an anti-bacterial solution between treatments to avoid cross contamination.

When treating your patient's face and neck area with blue or infrared light, it is essential to protect your client's eyes. In order to ensure proper protection and completely safeguard your client, apply the provided disposable LED eye aids under the standard LIGHTWAVE™ goggles. Optional metal block-out goggles are available for those clients who find the use of the disposable LED eye aids uncomfortable.

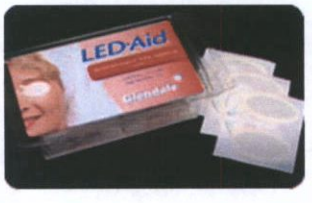
When treating other areas of the body (face and neck excluded), LIGHTWAVE™ recommends that the patient close their eyes for the entire duration of the treatment.

The operator does not directly view the light source for an extended period of time and therefore has a higher Maximum Permissible Exposure time. Due to the increased MPE time, the operator is not required to use protective eyewear. However, in order to properly protect the operator and limit their exposure time, IPL or Laser goggles are recommended.



Standard LIGHTWAVE supplied goggles

Optional LIGHTWAVE metal block-out goggles



LIGHTWAVE supplied disposable LED Aids

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 2- Contraindications for Light Therapy

Precautionary Information

The safety of light therapy has been tested and no significant adverse reactions have been noted. However, using light therapy when treating patients with specific high-risk conditions has not been thoroughly established. Therefore, do not treat children or patients with the following conditions:

- **Acute or Cutaneous Porphyria**
- **Lupus Erythematosus**
- **Photophobia**
- **Exogenous Eczema**
- **Epilepsy & Seizures**
- **Hypomelanism (albinism)**
- **Skin Cancer**
- **Eye disease/retinal abnormalities**
- **Pregnancy**

Contraindications

The following medications have been known to cause photosensitivity, or a reaction to normal amounts of UVA or in some cases intense red and blue light. If possible, medications listed below need to be suspended for a minimum of one week before undergoing light therapy. If it is not possible to discontinue the use of a medication then your client must consult with their doctor before undergoing light therapy while continuing on the medication. It is further imperative that your client check with his/her doctor before discontinuing any prescribed medications.

Amiodarone, Chlorpromazine, Oral Isotretinoin, Topical Isotretinoin, Haloperidol, Trifluoperazine, Griseofulvin, Tetracycline, Norfloxacin, Ofloxacin, Nalidixic acid, Ciprofloxacin, Minocycline Oxytetracycline , Demeclocycline, Lymecycline, Methotrexate

***If a patient is taking Auranofin (Ridaura®), they are not a candidate for light therapy.**

The above drugs are currently the most common medications associated with photosensitivity and are by no means a complete list of all photosensitive medications. If a particular medication is not listed above, please refer to the manufacturer's information sheet for any precautions relating to photo sensitivity. Herbs and over the counter medications such as psoralen and St. John's Wort can also cause sensitivity to light so it is important to stress to your client that they disclose any and all medications or herbs they are currently taking.

Specific to Acne Patients

In rare cases cystic acne can increase rather than improve. Cystic acne patients should discontinue the light therapy treatment if they react unfavorably to the treatment. For any acne patient, if their condition worsens instead of improves, the solution is less light not more. Please refer to the specific protocol outlined in the professional section of this manual before treating acne patients.

If an acne patient has been treated with a topical photosensitizer such as 5-ALA in the past 48 hours, they may not undergo light therapy until all of the photosensitizer has been absorbed by the body. If they do undergo light therapy within 48 hours, they run the risk of re-activating the photosensitizer which can cause severe erythema, peeling and significant discomfort.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 3- Placement of Panel

The positioning and proper placement of the panel is extremely important. If the panel is not correctly placed over the treatment area, the dosage of light delivered can vary and adversely affect the treatment outcome.

WARNING: Use Carefully. May cause serious burns. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, laying on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin. If you place the panel directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

Please follow these simple steps when positioning the panel:

1. Select the desired treatment area; keeping in mind the treatment area can not exceed the size of the panel as the treatment is localized to the treatment area only. If the desired treatment area exceeds the panel size, additional treatments will need to be performed on the treatment area that extends beyond the panel boundaries.

2. The LED panel is designed with six adjustable joints and squares so that the panel can lay flat when treating surfaces such as the back or contour around a selected target area such as the face. Make sure the panel is adjusted at the joint.

3. When positioning the panel for a cosmetic treatment, evenly place the individual LED squares 1 inch from the target treatment area. When treating an uneven surface such as the face, the furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the panel at all times should remain within ½-1 inch from the surface of the target area. If the panel extends beyond the area of concern, the additional area will be exposed to light therapy. The further away the area is from the panel, the less photon energy the area will absorb. If you do not want to expose an area of skin to light, the excess skin can be covered with a thick cloth.

4. When positioning the panel for a treatment addressing a concern dealing with pain and discomfort within the body, the panel needs to increase the skin temperature to 104°F - 113°F and maintain the elevated temperature throughout the duration of the treatment. In order to do so, you must evenly place the individual LED squares ½ inch from the target treatment area. When treating an uneven surface, the furthest extended point should be no more than ½ inch and no closer than ¼ inch from the LED panel. In order to ensure proper dose and temperature, the panel at all times should remain within ¼-½ inch from the surface of the target area. The IR setting on the panel is capable of raising and maintaining an elevated area temperature ranging from 104°F-109°F if the panel is correctly placed over the area of concern. Proper placement of the panel is essential in treating inflammation of the joints and muscle discomfort. If the panel is not within ½ of the target area, it is not capable of maintaining an elevated temperature throughout the treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA K00104

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 28, 2009

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

510k Number: K082586

Product: LIGHTWAVE PROFESSIONAL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

K 082586/5

RETURN RECEIPT REQUESTED

May 26, 2009

Office of Device Evaluation
U. S. Food and Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FDA CDRH DMC
MAY 27 2009
Received

Reference: Additional Information Response for 510(k): K082586

Dear Sir/Madam:

Pursuant to the above-captioned 510(k) submissions, the following information is being submitted to Document Mail Center per the FDA letter dated May 1, 2009 from the reviewer, Richard P. Weiblinger, FDA requesting additional information.

We have prepared our responses in the order of the questions presented to us by the letter as follows:

Question 1:

Response 1:

Question 2:

Response 2:

We trust that the aforementioned responses will be satisfactory.

If you have any questions, or require additional information, please feel free to call me at (704) 843-1675 or (5l6) 482-9001 or e-mail me at maria@mdiconsultants.com.

Sincerely,

Maria F. Griffin/Da

Maria F. Griffin
Official Correspondent for
Lightwave Technologies, LLC
Attachments

K27

A complete list of Attachments is annexed hereto.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Question 1 (via telephone):

(b) (4)

[redacted]

Question 2 (via telephone):

(b) (4)

[redacted]

Question 3 (via telephone):

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Response 3

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LIST OF ATTACHEMNTS

Attachment 1	User Manual
Attachment 2	Statement
Attachment 3	Page 39 of the Predicate User Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRHPOSTATUS@fda.hhs.gov or 301-796-8118

DJA x00109

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NOTICE: READ BEFORE OPERATING

The information supplied throughout this document should be used only as a guideline and does not constitute or replace medical advice. LIGHTWAVE™ Technologies is registered with the FDA.

- This manual must be kept for quick reference on use, cautions, maintenance and repair.
- Read this manual in its entirety before using the LIGHTWAVE™ system.
- Improper use of the LIGHTWAVE™ system can void the warranty. Please familiarize yourself with the limitations of the warranty and proper handling and storage of the system.
- The goggles included with the LIGHTWAVE™ unit are to be used at all times while operating any setting on the system. Due to the specific protection of the safety eye wear; they should never be used as protection with any other light or laser systems. Company issued replacement plastic goggles, stainless steel framed safety glasses, and disposable LED shields have all been shown to be effective. These varieties of eye protection are available for purchase through LIGHTWAVE™ Technologies.
- Should the panel ever come in direct contact with the skin for any reason, LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol swab to avoid cross contamination. NEVER clean the panel when the unit is powered "ON."
- WARNING: Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the LIGHTWAVE Professional Deluxe by children or incapacitated persons may be dangerous.

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No part of this instruction manual may be used to make derivative works based upon the original. No part of this information may be passed on, written down or used for commercial or private reproduction or any other purpose not specifically mentioned unless and until LIGHTWAVE™ Technologies LLC gives its written permission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of Contents

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00111

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Getting Started

LIGHTWAVE™ systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

Introduction

Thank you for choosing LIGHTWAVE™. This operating manual contains information on our LIGHTWAVE™ Professional light therapy system.

Below you will find a general overview of the LIGHTWAVE™ system as well as detailed sections throughout this guide providing you comprehensive knowledge of our systems' operation, and guidance on how to maintain it for years to come.

Please read the safety sections in their entirety before operating the system.

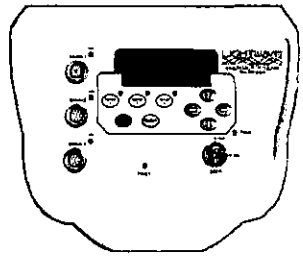
Again, we appreciate your confidence in LIGHTWAVE™ Technologies. Our customer care team welcomes any and all feedback with regard to our equipment. We can be reached by dialing toll-free at 866-999-6954.

System Overview

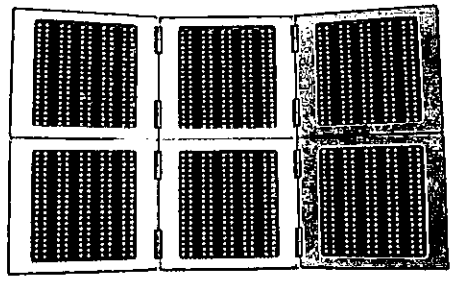
All LIGHTWAVE™ systems include a main unit and one accessory item.

Main Unit:

LIGHTWAVE's main unit features one touch button operation, a large LCD screen display, 3 accessory sockets, power supplies, operational software, and a locking on/off key switch.



Panels:



LIGHTWAVE's basic accessory item is the LED arm panel. It utilizes Red (630 nm), Infrared (880 nm) and Blue (420 nm) wavelengths. However, multiple wavelengths should ever be used simultaneously, use only one wavelength at a time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them. Each panel contains movable sections with independent hinges allowing it to adjust and form around the area being treated. This allows the panel to maintain a uniform distance from the treatment area which enables an even amount of light to be distributed. Please refer to *Positioning the Panel* for specific details on placing the panel over the treatment area.

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System Specs and Details

Output Intensity	Red 112 mW/cm2 Infrared 82mW/cm2 Blue 86mW/cm2
Output Wavelength	Red 630nm Infrared 880nm Blue 420 nm
Bandwidth	Red 25nm +/- 5nm Infrared 25nm +/- 5nm Blue 25nm +/-- 5nm
Light Source	SL SMT LED
Pulse	CW & Variable
Energy	1-248 joules
Coverage Area	Up to 1668 cm2
Electrical Supply	AC 110v or 220v
Weight	50lbs
Size	58 in (h) x 24 in (w)
Color	White, Grey and Black

Storage

The main unit is shipped inside a pink anti-static bag. This bag must be retained for future shipping needs should they arise. Failure to do so will result in additional material and handling charges.

Thoroughly clean the panel after each use and prior to storing. Please see *User Maintenance* for specific cleaning instructions.

When not in use, store the main unit and panel in a dust free environment to prolong the life of your system.

User Maintenance

Power off and unplug the LIGHTWAVE™ main unit prior to cleaning the system.

Any time the panel comes in direct contact with the patient's skin or that of the operator; LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol pad to avoid cross contamination. This is for your protection and the protection of your clients. Do not spray the system or accessories directly with an anti-bacterial solution but rather dampen a cloth with the solution and wipe down the panel and main unit. Never clean the panel when the unit is powered "ON."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00113

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Safety Warnings

Listed below are general safety instructions that apply to the operation of LIGHTWAVE™ equipment. This list includes many, but not all, of the safety instructions. Also refer to the safety guidelines and warnings shown in the rest of this manual and on the equipment.

Read this manual and all safety labels in their entirety before operating the equipment.

Do not operate the LIGHTWAVE™ around water as this can increase the risk for electrical shock. If liquid is spilled on the equipment, unplug the unit and call LIGHTWAVE™ immediately.

Do not operate the LIGHTWAVE's™ equipment around flammable liquids or gases. Doing so increases the danger of possible fire or explosion.

Do not restrict airflow to the panel or main unit. See *Positioning the Panel* for specific details on placing the panel over the treatment area. Make sure all air flow openings on the main unit are unobstructed and have proper ventilation.

If any wiring becomes exposed on the LED panel cable or power cord, do not operate equipment. Doing so can increase the risk for possible electrical shock

Use only the power source provided with the LIGHTWAVE equipment. Static electricity can cause harm to your system.

LIGHTWAVE's™ equipment should have its own dedicated wall socket or power strip. Do not power the equipment with a shared power strip.

Do not place foreign objects on or near the LIGHTWAVE™ equipment.

Never attempt to open the main unit or panel. Doing so puts the operator at risk for electrical shock. In addition, it voids all warranties and will cause permanent damage to your system.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, laying on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin.

Specific Safety Warnings: Eyes

The LIGHTWAVE™ equipment has been classified as a CLASS 2 device. The device is only capable of emitting low powered light at certain wavelengths making it incapable of causing eye injury within the normal aversion response to intense light.

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The output of light produced during a treatment is greater than the recommended Maximum Permissible Exposure (MPE's) in the Blue and Infrared spectrum. It is absolutely imperative that the following guidelines are adhered to when operating the LIGHTWAVE™ equipment for the treatment of acne and for the temporary relief of minor muscle and joint pain.

The goggles provided with the LIGHTWAVE™ equipment are to be worn by the patient at all times when treatments are performed on or around the face and neck area. Goggles must be properly fitted over the retina and thoroughly disinfected with an anti-bacterial solution between treatments to avoid cross contamination.

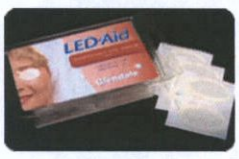
When treating your patient's face and neck area with blue or infrared light, it is essential to protect your client's eyes. In order to ensure proper protection and completely safeguard your client, apply the provided disposable LED eye aids under the standard LIGHTWAVE™ goggles. Optional metal block-out goggles are available for those clients who find the use of the disposable LED eye aids uncomfortable.

When treating other areas of the body (face and neck excluded), LIGHTWAVE™ recommends that the patient close their eyes for the entire duration of the treatment.

The operator does not directly view the light source for an extended period of time and therefore has a higher Maximum Permissible Exposure time. Due to the increased MPE time, the operator is not required to use protective eyewear. However, in order to properly protect the operator and limit their exposure time, IPL or Laser goggles are recommended.

Standard LIGHTWAVE supplied goggles

Optional LIGHTWAVE metal block-out goggles



LIGHTWAVE supplied disposable LED Aids

Contraindications

The safety of light therapy has been tested and no significant adverse reactions have been noted. However, using light therapy when treating patients with specific high-risk conditions has not been thoroughly established. Therefore, as a precaution LIGHTWAVE recommends not treating children or patients with the following conditions:

Acute or Cutaneous Porphyria, Lupus Erythematosus, Thyroid Problems, Photophobia Exogenous Eczema, Epilepsy & Seizures, Hypomelanism (albinism), Skin Cancer, Migraines Eye disease/retinal abnormalities, Diabetes, Pregnancy.

Specific to Acne Patients:
In rare cases cystic acne can increase rather than improve. Cystic acne patients should discontinue the light therapy treatment if they react unfavorably to the treatment. For any acne patient, if their condition worsens instead of improves, the solution is less light not more.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00115

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

The following medications have been known to cause light sensitivity. If possible, medications listed below must be suspended for a minimum of one week before undergoing light therapy. If it is not possible to discontinue the use of a medication then your client must consult with their doctor before undergoing light therapy while continuing on the medication. It is further imperative that your client check with his/her doctor before discontinuing any prescribed medications.

Anti-Arrhythmic:	**Amiodarone** (Pacerone® Cordarone® Aratac®)
	Chlorpromazine (Thorazine®, Chloramead®, Chlordryprom®, Chlor® Promanyl®, Largactil®, Promapar®, Promosol®, Terpium®, Sonazine®)
Acne:	**Oral Isotretinoin** (Accutane®, Accure®, Aknenormin®, Amnesteem®, Ciscutan®, Claravis®, Isohexal®, Isotroin®, Oratane®, Sotret®, Roaccutane®)
	Topical Isotretinoin (Isotrex®, Isotrexin®)
Anti-Psychotic:	**Haloperidol** (Haldol®)
	Trifluoperazine (Stelazine®, Clnazine®, Novoflurazine®, Pentazine®, Solazine®, Terfluzine®, Triflurin®, Tripazine®)
Anti-Fungal:	**Griseofulvin** (Grifulvin®)
Antibiotics:	**Tetracycline** (Helidac®, Terra-Cortril®, Terramycin®, Sumycin®, Actisite®, Bristacycline®, Actisite®, Tetrex®, Doxycycline®, Ciprofloxacin®)
	Norfloxacin (Noroxin®, Quinabic®, Janacin®)
	Ofloxacin (floxin®, Oxaldin®, Tarivid®)
	Nalidixic acid (NegGam®, Wintomylon®)
	Ciprofloxacin (Cipro®, Ciproxin®, Ciprobay®)
	Minocycline (Minomycin®, Minocin®, Arestin®, Akamin®, Aknemin®, Solodyn®, Dynacin®, Sebomin®)
	Oxytetracycline
	Demeclocycline
	Lymecycline
Cancer:	**Methotrexate** (MTX®, Aminopterin®, Ledertrexate®)
Arthritis:	**Auranofin** (Ridaura®)-***If a patient is taking this medication; they are not a candidate for light therapy.***

The above drugs are currently the most common medications associated with photosensitivity and are by no means a complete list of all photosensitive medications. Herbs and over the counter medications such as psoralen and St. John's Wort can also cause sensitivity to light so it is important to stress to your client that they disclose any and all medications or herbs they are currently taking.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00116

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

LIGHTWAVE Deluxe System

Intended 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00117

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Operating Instructions

Deluxe System Contents

1 – Control Unit
2 – Control Unit Keys
1 – 6ft Power Cord
1 - Stand with Casters and 2 Trays
1 - Arm with pole bracket
2 - 3 pc LED arm panels
1 - LED panel main cable
1- Power Surge Protector
1- Protective Eye Wear
1- User Manual and Protocol booklet

To Get Started

Image 1 - All LCU's come equipped with a 4-amp fuse to protect the unit from power surges. Always disconnect the power before accessing fuse.

Place the LIGHTWAVE™ Main Control Unit, (MCU) on a stable, flat surface or on the LIGHTWAVE™ stand. To turn on the LIGHTWAVE™ unit, connect the female end of the electrical power cord to the back of the unit. Plug the male connector into the **surge protector,** which needs to be connected to a standard 110v electrical outlet. Next, flip the On/Off switch to the **on (-)** position on the back of the MCU (See picture on the left).

Connecting LED Pads or Arm Assembly

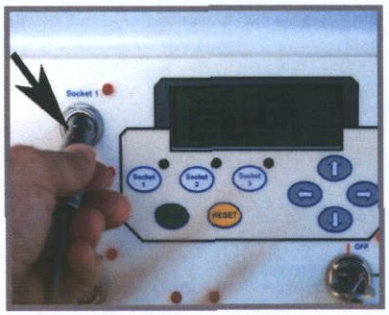


Image 2 –Be sure the red dot is pointing up before inserting the connector into the socket port.

In order to connect the LED Panel assembly, the operator must first identify the RED dot on the collar of the connector tip. The red dot aligns pointing directly upwards when connecting the panel to the main control unit. After connecting the panel cord to the main unit, the cord needs to be connected to the arm panel. When connecting the arm cord to the arm panel, the red dot aligns pointing directly downwards instead of upwards as it did when you connected the cord to the base. After connecting the LED panel, the operator can turn ON the power switch if it has not already been done, which is located on the back of the MCU (LED panel may be plugged in with the power on or off). Upon starting, the unit will move through a number of initial screens that identify the machine's version of software and the model number. Then the control screen will indicate the present status of each socket.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00118

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

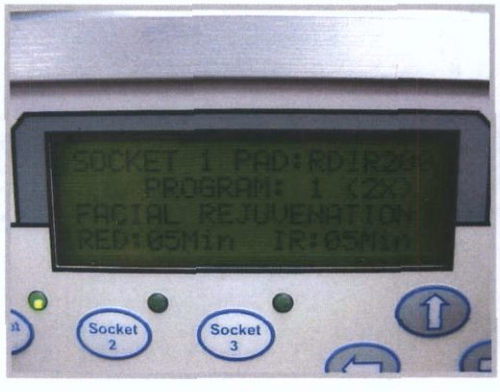
Setting the Preset Programs

When the panel is connected to the MCU, the green indicator nearest to the corresponding socket button is illuminated indicating a good connection between the panel and the MCU (if you have correctly connected the panel and the green light is not lit, please consult Tech Support).

*Image 3-The **Main Control Display** pictured to the left shows that a main panel is plugged into socket one and the green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button that corresponds to the panel that has just been connected will bring up the **Socket Status Display** for that socket. The socket status display should appear as below.

*Image 4-The **Socket Status Display** pictured to the right shows that a main panel is plugged into socket one. The green light next to the socket one button indicates that socket one is ready.*



Pressing the socket button again brings a blinking cursor to the program number. Using the up and down arrow keys allows the user to change from one program to the next. When the desired program is displayed, press enter, the blinking cursor will go away and the LIGHTWAVE™ unit is now ready to begin a treatment session. Pressing enter for a second time will start the treatment session. Please see *Performing Treatments* before initiating a treatment session.

Using the Machine "LOCK" Option

As an added safety feature, the operator can restrict the use of the machine from other users. By simply turning the key to the "OFF" position, the display will read "LOCKED" and no operations can be performed, completely disabling the LIGHTWAVE™ unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00119

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Using the "MENU"

The MENU can only be accessed from the **Main Control Display**. By pressing the RESET button, the user is sent to the Main Control Display screen. With the arrows blinking on either side of the word "MENU", press the ENTER button and the words similar to below will be shown. (Each one of the MENU options can be accessed by moving the blinking arrows with the up and down arrow keys.)

SET TIME AND DAY: Simply use the up and down arrow keys, along with ENTER to set the time and date.

ADD TREATMENTS: This function is for the units that are contracted on a pay per treatment program or other contract. Call Tech Support when using this menu.

RETURN: Returns the display to the Main Control Display.

Performing Treatments

Positioning the Panel

The proper placement of the panel is extremely important. If the panel is not correctly positioned over the treatment area, the dosage of light delivered can vary and affect the treatment outcome.

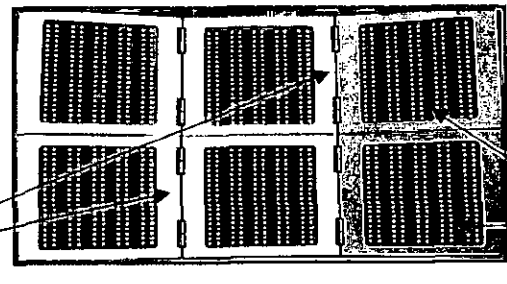
CAUTION: Never place the panel directly on open wounds, sunburns, or sensitive tissue. Restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin. If the panel is placed directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

NOTE: Never activate two separate wavelengths at the same time, only one wavelength should be used at one time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them.

Please follow these simple steps when positioning the panel:

1. Select the desired treatment area; keeping in mind the treatment area should not exceed the size of the panel. If the desired treatment area exceeds the panel size, additional treatments will need to be performed on the treatment area that extends beyond the panel boundaries.

2. The LED panel is designed with six adjustable joints and squares so that the panel will lay flat when treating surfaces such as the back or contour around a selected target area such as the face. Always adjust the panel at the joint.



DJA x00120

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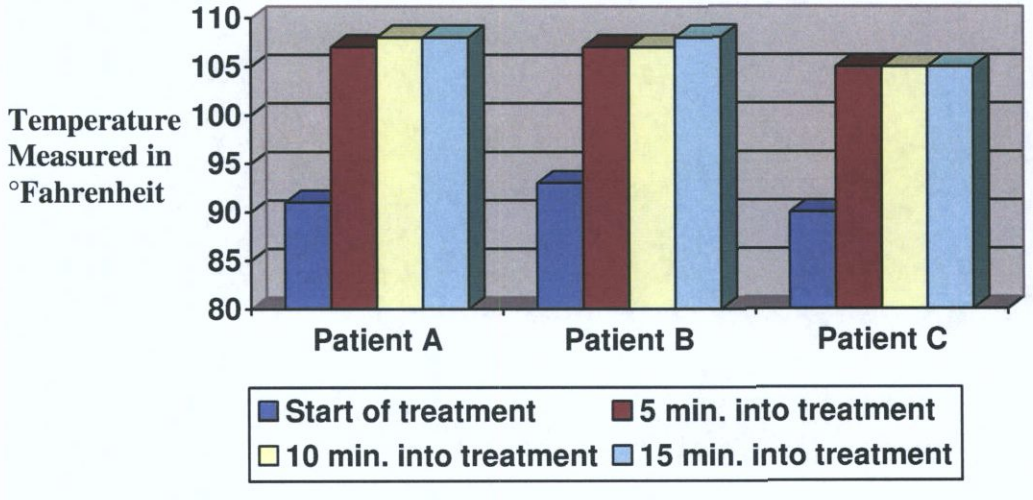
3. When positioning the panel for a cosmetic treatment, evenly place the individual LED squares 1 inch from the target treatment area. When treating an uneven surface such as the face, the furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the panel at all times should remain within ½-1 inch from the surface of the target area. If the panel extends beyond the area of concern, the additional area will be exposed to light therapy. The further away the area is from the panel, the less photon energy the area will absorb. If you do not want to expose an area of skin to light, the excess skin can be covered with a thick cloth.

4. When positioning the panel for a treatment addressing a concern dealing with pain and discomfort within the body, the panel needs to increase the skin temperature to 104°F -113°F and maintain the elevated temperature throughout the duration of the treatment. In order to do so, you must evenly place the individual LED squares ½ inch from the target treatment area. When treating an uneven surface, the furthest extended point should be no more than ½ inch and no closer than ¼ inch from the LED panel. In order to ensure proper dose and temperature, the panel at all times should remain within ¼-½ inch from the surface of the target area.

AVERAGE SKIN TEMPERATURE READINGS FOR IR SETTING



As noted from the chart above, three patients' temperature readings were taken over a 15 minute treatment span. Based on the performance data, the IR setting on the panel is capable of raising and maintaining an elevated area temperature ranging from 104°F-109°F if the panel is correctly placed over the area of concern. Proper placement of the panel is essential in treating inflammation of the joints and muscle discomfort. If the panel is not within ½ of the target area, it is not capable of maintaining an elevated temperature throughout the treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00121

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Starting Treatment and Treatment Dose

Once you have correctly set-up your system and properly positioned the LED panel, you are ready to start a treatment session. Before starting a treatment session, please read the *Protocol Usage Manual* so that you are familiar with the various treatment options.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Please read *Safety Warnings (pg. 5)* before starting a treatment.

Please follow the steps below to start a treatment:

1. Select the proper treatment program corresponding to the desired treatment area. Make sure the monitor exhibits the Socket Status Display screen (See image 4, pg. 10) by pressing the corresponding socket button to the matching treatment socket.

   The LIGHTWAVE Deluxe Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions. The red light is capable of delivering a standard dose of 126 Joules/cm² in 20 minutes.

   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. However, only one wavelength should be used at a time. No two wavelengths should ever be used simultaneously. The red light is capable of delivering a standard dose of 126 Joules/cm² in 20 minutes. The blue light is capable of delivering a standard dose of 48 Joules/cm² in 20 minutes.

   THE LIGHTWAVE Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The blue light is capable of delivering a standard dose of 48 Joules/cm² in 20 minutes.

   THE LIGHTWAVE Deluxe Red and Blue light combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The red light is capable of delivering a standard dose of 126 Joules/cm² in 20 minutes. The blue light is capable of delivering a standard dose of 48 Joules/cm² in 20 minutes.

   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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00122

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The Infrared light is capable of delivering a standard dose of 66 Joules/cm^2 in 20 minutes.

NOTE: Never activate two separate wavelengths at the same time, only one wavelength should be used at one time. The panel should only be connected to the socket that is intended to be used for that treatment regimen. Unused sockets should not have panels connected to them.

2. Confirm the proper program is displayed, and then press ENTER. The Red indicator should illuminate next to the socket that corresponds to the socket that was just started. As long as the Red indicator is lit, this socket is active. Do not remove the arm panel until the treatment is complete. If a patient feels uncomfortable in any way proceed with the following - **Note: To Stop a Treatment, Press the "RESET" button in the Socket Status Display Screen.** For multiple treatments, simultaneously, repeat above procedures for other sockets.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00123

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Troubleshooting

LIGHTWAVE's Basic Troubleshooting Guide

Problem	Possible Source	Mandatory Action
No Power	Power cable unplugged	Connect power cable to a working outlet
No Power	Surge Protector not on	Turn on surge protector
No Power	Power switch is set to "OFF" position	Turn switch to "ON" position
Display shows "LOCKED"	Key is set to "ON" position	Turn key to "OFF" position
System Shows "Panel READ ERROR"	Static build up	Unplug all devices from system and turn power off. Wait 2 minutes and turn on system without ay devices plugged in. Once system is completely on plug in devices one at a time.
"This device requires socket 1"	Device that requires socket 1 was plugged into socket 2 or 3.	Unplug device from socket 2 or 3 and plug into socket 1.
Program not turning on	Device not plugged into system correctly	Ensure that the device is plugged into the system and it is registered on the "Main Menu" screen.
Displays "Call Tech Support"		Call Tech support at 1-866-999-6954
Main Unit keeps asking for a confirmation #		Call Tech support for code

If the above actions do not rectify the problem or if an error occurs not listed on in the table, please call our help desk at 1-866-999-6954.

DJA x00124

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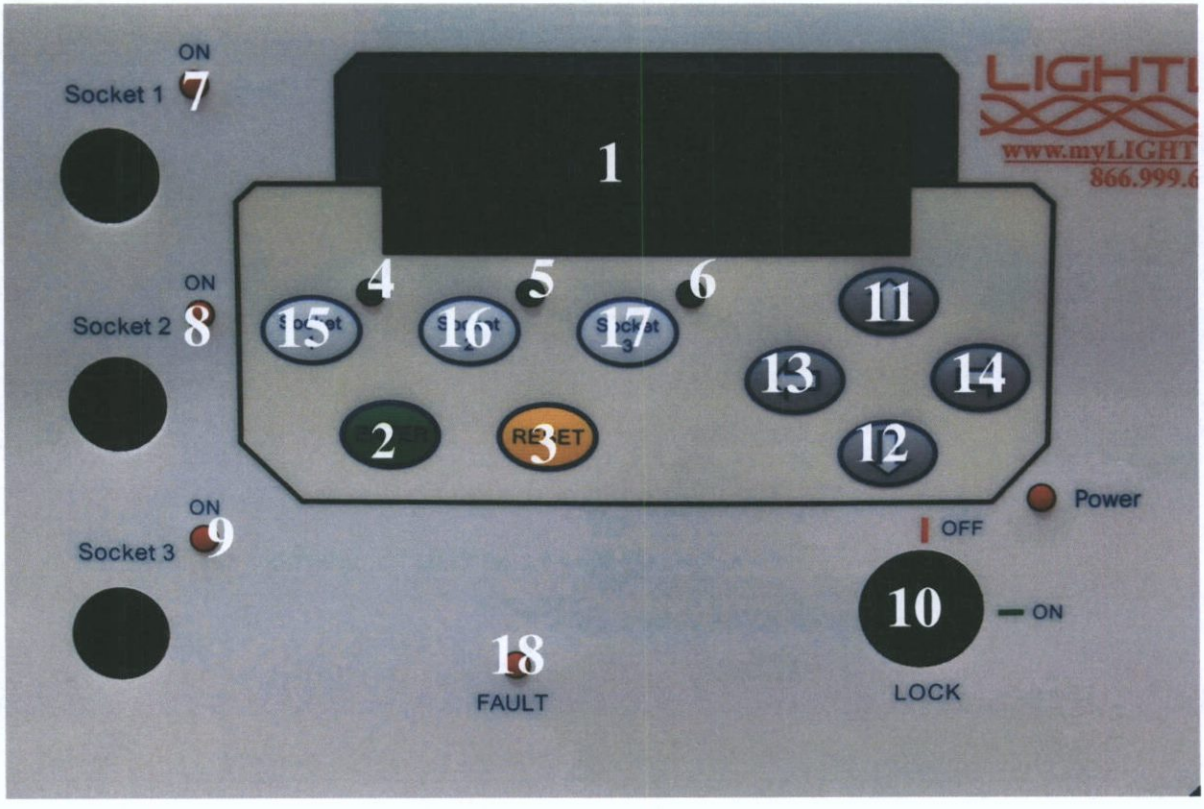
Control Unit Membrane Index

MEMBRANE CONTROL SCREEN



1. LCD Display
2. Enter Button
3. Reset Button
4. Socket 1 Display Status Button
5. Socket 2 Display Status Button
6. Socket 3 Display Status Button
7. Socket 1 and Socket 1 Active Indicator
8. Socket 2 and Socket 2 Active Indicator
9. Socket 3 and Socket 3 Active Indicator
10. LOCK
11. Up Arrow
12. Down Arrow
13. Left Arrow
14. Right Arrow
15. Socket 1 Button
16. Socket 2 Button
17. Socket 3 Button
18. Fault Indicator

Please call us toll free at (866) 999 - 6954 Monday – Friday MST from 8:00 – 5:00 so we may address any questions or concerns you have with regard to this manual, protocols, usage, etc.

Once again, thank you for choosing LIGHTWAVE™.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00125

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Attachment 2

2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
1-866-999-6954 (TF)
(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

RETURN RECEIPT REQUESTED

May 13, 2009

Office of Device Evaluation
U. S. Food & Drug Administration
Center for Devices & Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: Additional Information for 510(k) Number K082586

Dear Sir/Madam:

Our LIGHTWAVE Deluxe System is equivalent to our predicate device as the doses and times administered by each system are identical. Per page 39 of Omnilux's Operating Manual and page 13 of the LIGHTWAVE Operating Manual, the regimes are written using the same identical verbiage so that the outcome from the treatments will be exactly the same.

Thank you for your consideration in this matter.

Sincerely,

Michael Poling
LIGHTWAVE Technologies, LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

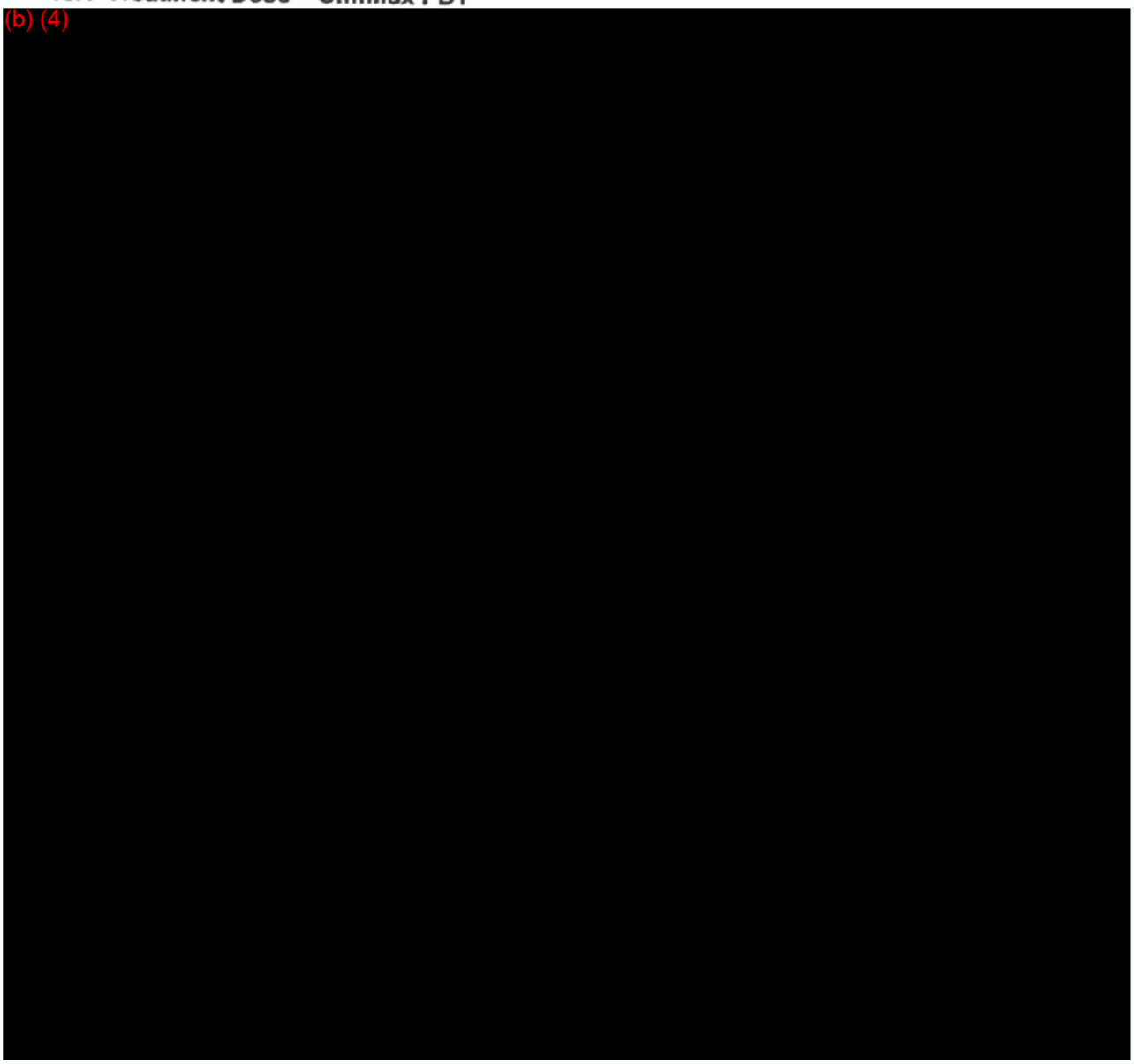
DJA x00126

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18. **Attachment 3**

18 Treatment Dose and Distance

18.1 Treatment Dose – Omnilux PDT

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA k00063

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 24, 2009

LIGHTWAVE TECHNOLOGIES LLC
C/O MDI CONSULTANTS, INC
55 NORTHERN BLVD SUITE 200
GREAT NECK, NEW YORK 11021
UNITED STATES
ATTN: MARIA F. GRIFFIN

510k Number: K082586

Product: LIGHTWAVE PROFESSIONAL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00064

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K082586 /S3

2222 W. Parkside Lane, Ste 111
Phoenix, AZ 85027
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(602) 548-8818 (Fax)
www.myLIGHTWAVE.com

LIGHTWAVE Technologies L.L.C.

RETURN RECEIPT REQUESTED

FDA CDRH DMC

NOV 23 2009

Received

K-S1

November 20, 2009

Office of Device Evaluation
U. S. Food and Drug Administration
Center for Devices & Radiological Health
Document Mail Center – WO66 Room G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference: Additional Information Response for 510(k): K082586

Dear Sir/Madam:

Pursuant to the above-captioned 510(k) submissions, the following information is being submitted to Document Mail Center per the FDA letter dated May 29, 2009 from the reviewer, Richard P. Weiblinger, FDA requesting additional information.

We have prepared our responses in the order of the questions presented to us by the letter as follows:

Question 1:

Response 1:

Question 2:

Response 2:

We trust that the aforementioned responses will be satisfactory.

If you have any questions, or require additional information, please feel free to call me at (704) 843-1675 or (5l6) 482-9001 or e-mail me at maria@mdiconsultants.com.

Sincerely,

Maria F. Griffin /da

Maria F. Griffin
Official Correspondent for
Lightwave Technologies, LLC
Attachments

A complete list of Attachments is annexed hereto.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00065

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

Question 1 (via telephone with Rick Weiblinger and Richard Felton):

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00066

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

LIST OF ATTACHMENTS

Attachment 1	Updated User Manual
Attachment 2	510(k) Summary
Attachment 3	Updated Comparison Chart

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00067

Records processed under FOIA Request 2017-5756; Released by CDRH on 08-30-18.

NOTICE: READ BEFORE OPERATING

The information supplied throughout this document should be used only as a guideline and does not constitute or replace medical advice. LIGHTWAVE™ Technologies is registered with the FDA.

- This manual must be kept for quick reference on use, cautions, maintenance and repair.
- Read this manual in its entirety before using the LIGHTWAVE™ system.
- Improper use of the LIGHTWAVE™ system can void the warranty. Please familiarize yourself with the limitations of the warranty and proper handling and storage of the system.
- The goggles included with the LIGHTWAVE™ unit are to be used at all times while operating any setting on the system. Due to the specific protection of the safety eye wear; they should never be used as protection with any other light or laser systems. Company issued replacement plastic goggles, stainless steel framed safety glasses, and disposable LED shields have all been shown to be effective. These varieties of eye protection are available for purchase through LIGHTWAVE™ Technologies.
- Should the panel ever come in direct contact with the skin for any reason, LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol swab to avoid cross contamination. NEVER clean the panel when the unit is powered "ON."
- WARNING: Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the LIGHTWAVE Professional Deluxe by children or incapacitated persons may be dangerous.

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Getting Started

LIGHTWAVE™ systems are designed to be as simplistic as possible for the user to operate while still providing outstanding results.

Introduction

Thank you for choosing LIGHTWAVE™. This operating manual contains information on our LIGHTWAVE™ Professional light therapy system.

Below you will find a general overview of the LIGHTWAVE™ system as well as detailed sections throughout this guide providing you comprehensive knowledge of our systems' operation, and guidance on how to maintain it for years to come.

Please read the safety sections in their entirety before operating the system.

Again, we appreciate your confidence in LIGHTWAVE™ Technologies. Our customer care team welcomes any and all feedback with regard to our equipment. We can be reached by dialing toll-free at 866-999-6954.

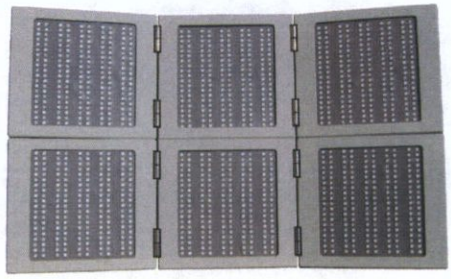
System Overview

All LIGHTWAVE™ systems include a main unit and one accessory item.

Main Unit:

LIGHTWAVE's main unit features one touch button operation, a large LCD screen display, 3 accessory sockets, power supplies, operational software, and a locking on/off key switch.

Panels:



LIGHTWAVE's basic accessory item is the LED arm panel. It utilizes Red (630 nm), Infrared (880 nm) and Blue (420 nm) wavelengths in a single panel. However, it utilizes only one channel or wavelength at a time and is not capable of operating multiple wavelengths simultaneously Unused sockets should not have panels connected to them. Each panel contains movable sections with independent hinges allowing it to adjust and form around the area being treated. This allows the panel to maintain a uniform distance from the treatment area which enables an even amount of light to be distributed. Please refer to *Positioning the Panel* for specific details on placing the panel over the treatment area.

System Specs and Details

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Output Intensity	Red 112 mW/cm2 Infrared 82mW/cm2 Blue 86mW/cm2
Output Wavelength	Red 630nm Infrared 880nm Blue 420 nm
Bandwidth	Red 25nm +/- 5nm Infrared 25nm +/- 5nm Blue 25nm +/-- 5nm
Light Source	SL SMT LED
Pulse	CW & Variable
Energy	1-248 joules
Coverage Area	Up to 1668 cm2
Electrical Supply	AC 110v or 220v
Weight	50lbs
Size	58 in (h) x 24 in (w)
Color	White, Grey and Black

Storage

The main unit is shipped inside a pink anti-static bag. This bag must be retained for future shipping needs should they arise. Failure to do so will result in additional material and handling charges.

Thoroughly clean the panel after each use and prior to storing. Please see *User Maintenance* for specific cleaning instructions.

When not in use, store the main unit and panel in a dust free environment to prolong the life of your system.

User Maintenance

Power off and unplug the LIGHTWAVE™ main unit prior to cleaning the system.

Any time the panel comes in direct contact with the patient's skin or that of the operator; LIGHTWAVE™ strongly suggests cleaning the panel with an anti-bacterial solution such as an alcohol pad to avoid cross contamination. This is for your protection and the protection of your clients. Do not spray the system or accessories directly with an anti-bacterial solution but rather dampen a cloth with the solution and wipe down the panel and main unit. Never clean the panel when the unit is powered "ON."

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Safety Warnings

Listed below are general safety instructions that apply to the operation of LIGHTWAVE™ equipment. This list includes many, but not all, of the safety instructions. Also refer to the safety guidelines and warnings shown in the rest of this manual and on the equipment.

Read this manual and all safety labels in their entirety before operating the equipment.

Do not operate the LIGHTWAVE™ around water as this can increase the risk for electrical shock. If liquid is spilled on the equipment, unplug the unit and call LIGHTWAVE™ immediately.

Do not operate the LIGHTWAVE's™ equipment around flammable liquids or gases. Doing so increases the danger of possible fire or explosion.

Do not restrict airflow to the panel or main unit. See *Positioning the Panel* for specific details on placing the panel over the treatment area. Make sure all air flow openings on the main unit are unobstructed and have proper ventilation.

If any wiring becomes exposed on the LED panel cable or power cord, do not operate equipment. Doing so can increase the risk for possible electrical shock

Use only the power source provided with the LIGHTWAVE equipment. Static electricity can cause harm to your system.

LIGHTWAVE's™ equipment should have its own dedicated wall socket or power strip. Do not power the equipment with a shared power strip.

Do not place foreign objects on or near the LIGHTWAVE™ equipment.

Never attempt to open the main unit or panel. Doing so puts the operator at risk for electrical shock. In addition, it voids all warranties and will cause permanent damage to your system.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Never place the panel directly on open wounds, sunburns, or sensitive tissue. Wrapping, laying on, or restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin.

Specific Safety Warnings: Eyes

The LIGHTWAVE™ equipment has been classified as a CLASS 2 device. The device is only capable of emitting low powered light at certain wavelengths making it incapable of causing eye injury within the normal aversion response to intense light.

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The output of light produced during a treatment is greater than the recommended Maximum Permissible Exposure (MPE's) in the Blue and Infrared spectrum. It is absolutely imperative that the following guidelines are adhered to when operating the LIGHTWAVE™ equipment for the treatment of acne and for the temporary relief of minor muscle and joint pain.

The goggles provided with the LIGHTWAVE™ equipment are to be worn by the patient at all times when treatments are performed on or around the face and neck area. Goggles must be properly fitted over the retina and thoroughly disinfected with an anti-bacterial solution between treatments to avoid cross contamination.

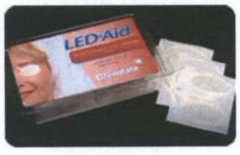
When treating your patient's face and neck area with blue or infrared light, it is essential to protect your client's eyes. In order to ensure proper protection and completely safeguard your client, apply the provided disposable LED eye aids under the standard LIGHTWAVE™ goggles. Optional metal block-out goggles are available for those clients who find the use of the disposable LED eye aids uncomfortable.

When treating other areas of the body (face and neck excluded), LIGHTWAVE™ recommends that the patient close their eyes for the entire duration of the treatment.

The operator does not directly view the light source for an extended period of time and therefore has a higher Maximum Permissible Exposure time. Due to the increased MPE time, the operator is not required to use protective eyewear. However, in order to properly protect the operator and limit their exposure time, IPL or Laser goggles are recommended.

Standard LIGHTWAVE supplied goggles

Optional LIGHTWAVE metal block-out goggles



LIGHTWAVE supplied disposable LED Aids

Contraindications

The safety of light therapy has been tested and no significant adverse reactions have been noted. However, using light therapy when treating patients with specific high-risk conditions has not been thoroughly established. Therefore, as a precaution LIGHTWAVE recommends not treating children or patients with the following conditions:

Acute or Cutaneous Porphyria, Lupus Erythematosus, Thyroid Problems, Photophobia Exogenous Eczema, Epilepsy & Seizures, Hypomelanism (albinism), Skin Cancer, Migraines Eye disease/retinal abnormalities, Diabetes, Pregnancy.

Specific to Acne Patients:
In rare cases cystic acne can increase rather than improve. Cystic acne patients should discontinue the light therapy treatment if they react unfavorably to the treatment. For any acne patient, if their condition worsens instead of improves, the solution is less light not more.

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The following medications have been known to cause light sensitivity. If possible, medications listed below must be suspended for a minimum of one week before undergoing light therapy. If it is not possible to discontinue the use of a medication then your client must consult with their doctor before undergoing light therapy while continuing on the medication. It is further imperative that your client check with his/her doctor before discontinuing any prescribed medications.

Anti-Arrhythmic:	**Amiodarone** (Pacerone® Cordarone® Aratac®)
	Chlorpromazine (Thorazine®, Chloramead®, Chlordryprom®, Chlor® Promanyl®, Largactil®, Promapar®, Promosol®, Terpium®, Sonazine®)
Acne:	**Oral Isotretinoin** (Accutane®, Accure®, Aknenormin®, Amnesteem®, Ciscutan®, Claravis®, Isohexal®, Isotroin®, Oratane®, Sotret®, Roaccutane®)
	Topical Isotretinoin (Isotrex®, Isotrexin®)
Anti-Psychotic:	**Haloperidol** (Haldol®)
	Trifluoperazine (Stelazine®, Clnazine®, Novoflurazine®, Pentazine®, Solazine®, Terfluzine®, Triflurin®, Tripazine®)
Anti-Fungal:	**Griseofulvin** (Grifulvin®)
Antibiotics:	**Tetracycline** (Helidac®, Terra-Cortril®, Terramycin®, Sumycin®, Actisite®, Bristacycline®, Actisite®, Tetrex®, Doxycycline®, Ciprofloxacin®)
	Norfloxacin (Noroxin®, Quinabic®, Janacin®)
	Ofloxacin (floxin®, Oxaldin®, Tarivid®)
	Nalidixic acid (NegGam®, Wintomylon®)
	Ciprofloxacin (Cipro®, Ciproxin®, Ciprobay®)
	Minocycline (Minomycin®, Minocin®, Arestin®, Akamin®, Aknemin®, Solodyn®, Dynacin®, Sebomin®)
	Oxytetracycline
	Demeclocycline
	Lymecycline
Cancer:	**Methotrexate** (MTX®, Aminopterin®, Ledertrexate®)
Arthritis:	**Auranofin** (Ridaura®)-***If a patient is taking this medication; they are not a candidate for light therapy.***

The above drugs are currently the most common medications associated with photosensitivity and are by no means a complete list of all photosensitive medications. Herbs and over the counter medications such as psoralen and St. John's Wort can also cause sensitivity to light so it is important to stress to your client that they disclose any and all medications or herbs they are currently taking.

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LIGHTWAVE Deluxe System

Intended 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 Infrared light combination is intended to emit energy in the red and infrared 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.

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Operating Instructions

Deluxe System Contents

1 – Control Unit
2 – Control Unit Keys
1 – 6ft Power Cord
1 - Stand with Casters and 2 Trays
1 - Arm with pole bracket
2 - 3 pc LED arm panels
1 - LED panel main cable
1- Power Surge Protector
1- Protective Eye Wear
1- User Manual and Protocol booklet

To Get Started

Image 1 - All LCU's come equipped with a 4-amp fuse to protect the unit from power surges. Always disconnect the power before accessing fuse.

Place the LIGHTWAVE™ Main Control Unit, (MCU) on a stable, flat surface or on the LIGHTWAVE™ stand. To turn on the LIGHTWAVE™ unit, connect the female end of the electrical power cord to the back of the unit. Plug the male connector into the **surge protector,** which needs to be connected to a standard 110v electrical outlet. Next, flip the On/Off switch to the **on (-)** position on the back of the MCU (See picture on the left).

Connecting LED Pads or Arm Assembly

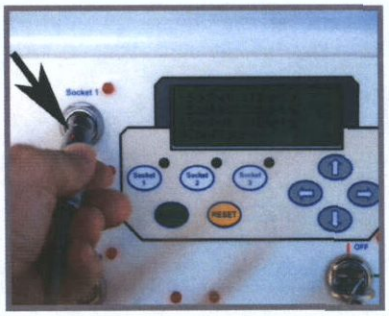

Image 2 –Be sure the red dot is pointing up before inserting the connector into the socket port.

In order to connect the LED Panel assembly, the operator must first identify the RED dot on the collar of the connector tip. The red dot aligns pointing directly upwards when connecting the panel to the main control unit. After connecting the panel cord to the main unit, the cord needs to be connected to the arm panel. When connecting the arm cord to the arm panel, the red dot aligns pointing directly downwards instead of upwards as it did when you connected the cord to the base. After connecting the LED panel, the operator can turn ON the power switch if it has not already been done, which is located on the back of the MCU (LED panel may be plugged in with the power on or off). Upon starting, the unit will move through a number of initial screens that identify the machine's version of software and the model number. Then the control screen will indicate the present status of each socket.

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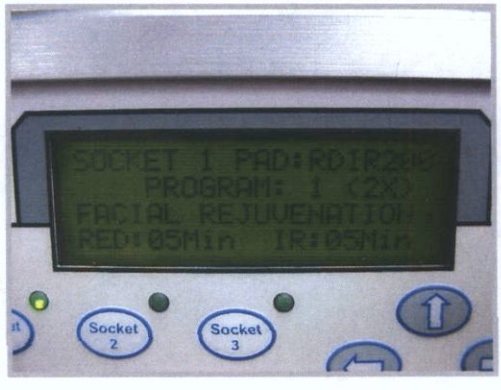
Setting the Preset Programs

When the panel is connected to the MCU, the green indicator nearest to the corresponding socket button is illuminated indicating a good connection between the panel and the MCU (if you have correctly connected the panel and the green light is not lit, please consult Tech Support).

*Image 3-The **Main Control Display** pictured to the left shows that a main panel is plugged into socket one and the green light next to the socket one button indicates that socket one is ready.*

Pressing the socket button that corresponds to the panel that has just been connected will bring up the **Socket Status Display** for that socket. The socket status display should appear as below.

*Image 4-The **Socket Status Display** pictured to the right shows that a main panel is plugged into socket one. The green light next to the socket one button indicates that socket one is ready.*



Pressing the socket button again brings a blinking cursor to the program number. Using the up and down arrow keys allows the user to change from one program to the next. When the desired program is displayed, press enter, the blinking cursor will go away and the LIGHTWAVE™ unit is now ready to begin a treatment session. Pressing enter for a second time will start the treatment session. Please see *Performing Treatments* before initiating a treatment session.

Using the Machine "LOCK" Option

As an added safety feature, the operator can restrict the use of the machine from other users. By simply turning the key to the "OFF" position, the display will read "LOCKED" and no operations can be performed, completely disabling the LIGHTWAVE™ unit.

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Using the "MENU"

The MENU can only be accessed from the **Main Control Display**. By pressing the RESET button, the user is sent to the Main Control Display screen. With the arrows blinking on either side of the word "MENU", press the ENTER button and the words similar to below will be shown. (Each one of the MENU options can be accessed by moving the blinking arrows with the up and down arrow keys.)

SET TIME AND DAY: Simply use the up and down arrow keys, along with ENTER to set the time and date.

ADD TREATMENTS: This function is for the units that are contracted on a pay per treatment program or other contract. Call Tech Support when using this menu.

RETURN: Returns the display to the Main Control Display.

Performing Treatments

Positioning the Panel

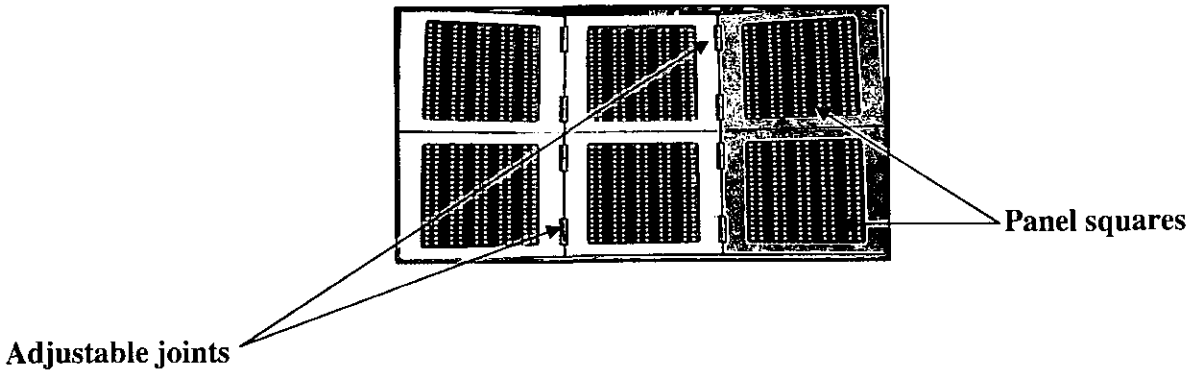
The proper placement of the panel is extremely important. If the panel is not correctly positioned over the treatment area, the dosage of light delivered can vary and affect the treatment outcome.

CAUTION: Never place the panel directly on open wounds, sunburns, or sensitive tissue. Restricting airflow greatly increases the panel temperature. It is important to let air flow between the panel and the client's skin. If the panel is placed directly on the patient's skin, airflow can become constricted and possible irritation or burning of the skin can occur.

Please follow these simple steps when positioning the panel:

1. Select the desired treatment area; keeping in mind the treatment area should not exceed the size of the panel. If the desired treatment area exceeds the panel size, additional treatments will need to be performed on the treatment area that extends beyond the panel boundaries.

2. The LED panel is designed with six adjustable joints and squares so that the panel will lay flat when treating surfaces such as the back or contour around a selected target area such as the face. Always adjust the panel at the joint.



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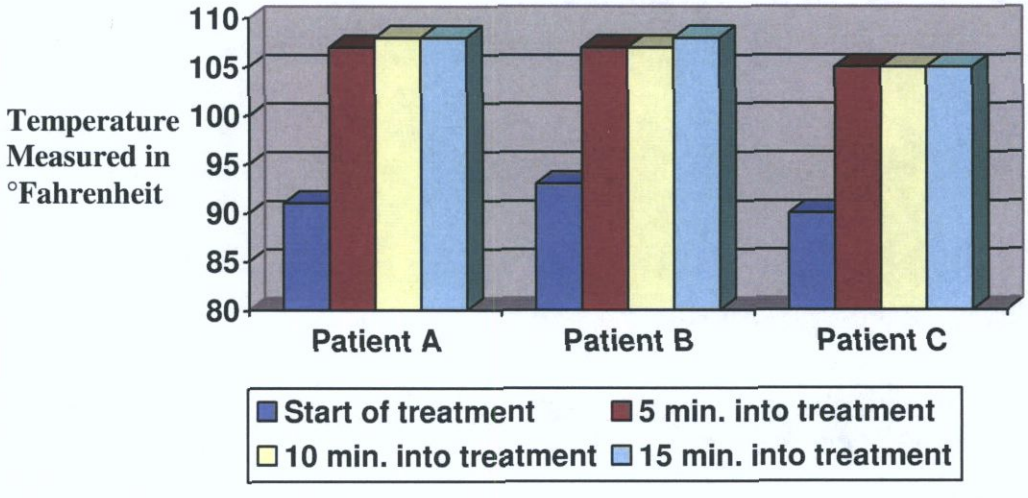
3. When positioning the panel for a cosmetic treatment, evenly place the individual LED squares 1 inch from the target treatment area. When treating an uneven surface such as the face, the furthest extended point such as the nose should be no more than 1 inch and no closer than a ½ inch from the LED panel. In order to ensure proper dose, the panel at all times should remain within ½-1 inch from the surface of the target area. If the panel extends beyond the area of concern, the additional area will be exposed to light therapy. The further away the area is from the panel, the less photon energy the area will absorb. If you do not want to expose an area of skin to light, the excess skin can be covered with a thick cloth.

4. When positioning the panel for a treatment addressing a concern dealing with pain and discomfort within the body, the panel needs to increase the skin temperature to 104°F -113°F and maintain the elevated temperature throughout the duration of the treatment. In order to do so, you must evenly place the individual LED squares ½ inch from the target treatment area. When treating an uneven surface, the furthest extended point should be no more than ½ inch and no closer than ¼ inch from the LED panel. In order to ensure proper dose and temperature, the panel at all times should remain within ¼-½ inch from the surface of the target area.

AVERAGE SKIN TEMPERATURE READINGS FOR IR SETTING



As noted from the chart above, three patients' temperature readings were taken over a 15 minute treatment span. Based on the performance data, the IR setting on the panel is capable of raising and maintaining an elevated area temperature ranging from 104°F-109°F if the panel is correctly placed over the area of concern. Proper placement of the panel is essential in treating inflammation of the joints and muscle discomfort. If the panel is not within ½ of the target area, it is not capable of maintaining an elevated temperature throughout the treatment.

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Starting a Treatment

Once you have correctly set-up your system and properly positioned the LED panel, you are ready to start a treatment session. Before starting a treatment session, please read *each indication below to become* familiar with the various treatment options.

WARNING: Use Carefully. May cause serious burns if used incorrectly. Do not use over sensitive skin area or in the presence of poor circulation. The unattended use of LIGHTWAVE Professional Systems by children or incapacitated persons may be dangerous. Please read *Safety Warnings (pg. 5)* before starting a treatment.

Please follow the steps below to start a treatment:

1. Select the proper treatment program corresponding to the desired treatment area. Make sure the monitor exhibits the Socket Status Display screen (See image 4, pg. 10) by pressing the corresponding socket button to the matching treatment socket.

2. Confirm the proper program is displayed, and then press ENTER. The Red indicator should illuminate next to the socket that corresponds to the socket that was just started. As long as the Red indicator is lit, this socket is active. Do not remove the arm panel until the treatment is complete. If a patient feels uncomfortable in any way proceed with the following - **Note: To Stop a Treatment, Press the "RESET" button in the Socket Status Display Screen. Turning the key to the lock position and powering down the system will also immediately stop a treatment session.**

Clinical Applications

TREATING MILD TO MODERATE ACNE

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. However, only one wavelength should be used at a time. Never use blue and red simultaneously as this can reduce the treatment efficacy. The red light is capable of delivering a standard dose of 126 Joules/cm² in 20 minutes. The blue light is capable of delivering a standard dose of 48 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment

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and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system; never using blue and red simultaneously as this can reduce the treatment efficacy. Please refer to *Starting a Treatment (pg. 13).* An initial eight treatment series starting with blue is recommended for this protocol over a 4 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week eight, documenting the client's progress. A follow-up appointment at week 8 is recommended.

	TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for MILD TO MODERATE ACNE (2 treatments per week with a minimum of 48 hours between treatment sessions. Never Use blue and red together as this reduces efficacy.)	Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take Several Bench Mark Photos. *If the photos are taken at the conclusion of the treatment the skin may appear flushed and red in color.*	✓			✓				✓
2	Cleanse the skin with an anti-bacterial wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Blue Light session.	✓		✓		✓		✓	
4	Start 20 minute Red Light session.		✓		✓		✓		✓

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TREATING MODERATE INFLAMMATORY ACNE

THE LIGHTWAVE Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The blue light is capable of delivering a standard dose of 48 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an anti-bacterial wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. An acne scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial eight treatment series of blue is recommended for this protocol over a 4 week period. The client should receive LED light therapy treatments two times a week for the first 4 weeks with at least 48 hours between treatment sessions. Before, during, and after photos should be taken at a minimum on week one, week four and week eight, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 8 LIGHTWAVE TREATMENT SESSIONS for MILD TO MODERATE ACNE (2 treatments per week with a minimum of 48 hours between treatment sessions. Never Use blue and red together as this reduces efficacy.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 3)	Session 7 (week 4)	Session 8 (week 4)
1	Take Several Bench Mark Photos.	✓			✓				✓
2	Cleanse the skin with an anti-bacterial wash.	✓	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Blue Light session.	✓	✓	✓	✓	✓	✓	✓	✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00082

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TREATING PERIORBITAL WRINKLES

THE LIGHTWAVE Deluxe Red and Infrared light combination is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The red light is capable of delivering a standard dose of 126 Joules/cm² in 20 minutes. The infrared light is capable of delivering a standard dose of 66 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Cleanse the entire target area with an exfoliating wash, removing all impurities and dead skin cells. For aged and/or sun damaged skin, additional exfoliation is recommended prior to starting the light therapy treatment. A micro-exfoliating scrub treatment and various chemical peels are all very effective in preparing the skin for an LED light therapy treatment.

Step Two: Precautions

Shield the patient's eyes by fitting the LED eye shields and protective goggles in place simultaneously, completely protecting the retina. The use of LIGHTWAVE issued LED eye shields and goggles are required to minimize brightness and to avoid any incidental eye exposure. Please refer to *Eye Safety Concerns* for complete information on proper protection.

Step Three: Treatment Instructions

Place the LED panel directly over the target area. Please refer to *Placement of Panel (pg. 11)* for more detailed information on positioning the panel. Once the panel has been properly placed, initiate the system. Please refer to *Starting a Treatment (pg. 13)*. An initial seven treatment series is recommended for this protocol over a 5 week period. The client should receive an infrared LED light therapy treatment two times a week for the first week with at least 48 hours between treatment sessions. During week two, the client should receive two LED red light therapy treatments with at least 48 hours between treatment sessions. During weeks three, four, and five, the client should receive one infrared light therapy treatment each week. Before, during, and after photos should be taken at a minimum on week one, week four and week seven, documenting the client's progress. A follow-up appointment at week 8 is recommended.

TREATMENT OVERVIEW: 7 LIGHTWAVE TREATMENT SESSIONS for PERIORBITAL WRINKLES (1-2 treatments per week with a minimum of 48 hours between treatment sessions. Never Use infrared and red together as this reduces efficacy.)		Session 1 (week 1)	Session 2 (week 1)	Session 3 (week 2)	Session 4 (week 2)	Session 5 (week 3)	Session 6 (week 4)	Session 7 (week 5)
1	Take Several Bench Mark Photos.	✓			✓			✓
2	Cleanse the skin with an exfoliating wash.	✓	✓	✓	✓	✓	✓	✓
3	Start 20 minute Infrared Light session.	✓	✓			✓	✓	✓
4	Start 20 minute Red Light session.			✓	✓			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00083

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TREATING MINOR MUSCLE AAND JOINT PAIN

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. The Infrared light is capable of delivering a standard dose of 66 Joules/cm² in 20 minutes.

Step One: Prepare the Skin

Caution should be taken not to place the panel directly on an open exposed cut or wound. The treatment area needs to be clean and free of any reflective agents that may affect the absorption of light.

Step Two: Precautions

When treating discomfort near the face and eye area, shield the patient's eyes by fitting the protective goggles in place, completely protecting the retina. The use of LIGHTWAVE issued goggles is required to minimize brightness and to avoid any incidental eye exposure. Please refer to *placement of Panel (pg.11)* for complete information on proper protection. If the area of concern is not near the face or eye area, the client still needs to close their eyes throughout the treatment session.

Step Three: Treatment Instructions

An initial minimum treatment series of four is recommended for this protocol over a two week period. The client should receive LED light therapy treatments two times a week with at least 24 hours between treatment sessions until the discomfort has subsided. The actual number of treatment sessions the client needs will depend greatly upon the degree of discomfort the client actually experiences. If necessary, a client may continue treatment twice a week for up to a total of five weeks before discontinuing treatment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Troubleshooting

LIGHTWAVE's Basic Troubleshooting Guide

Problem	Possible Source	Mandatory Action
No Power	Power cable unplugged	Connect power cable to a working outlet
No Power	Surge Protector not on	Turn on surge protector
No Power	Power switch is set to "OFF" position	Turn switch to "ON" position
Display shows "LOCKED"	Key is set to "ON" position	Turn key to "OFF" position
System Shows "Panel READ ERROR"	Static build up	Unplug all devices from system and turn power off. Wait 2 minutes and turn on system without ay devices plugged in. Once system is completely on plug in devices one at a time.
"This device requires socket 1"	Device that requires socket 1 was plugged into socket 2 or 3.	Unplug device from socket 2 or 3 and plug into socket 1.
Program not turning on	Device not plugged into system correctly	Ensure that the device is plugged into the system and it is registered on the "Main Menu" screen.
Displays "Call Tech Support"		Call Tech support at 1-866-999-6954
Main Unit keeps asking for a confirmation #		Call Tech support for code

If the above actions do not rectify the problem or if an error occurs not listed on in the table, please call our help desk at 1-866-999-6954.

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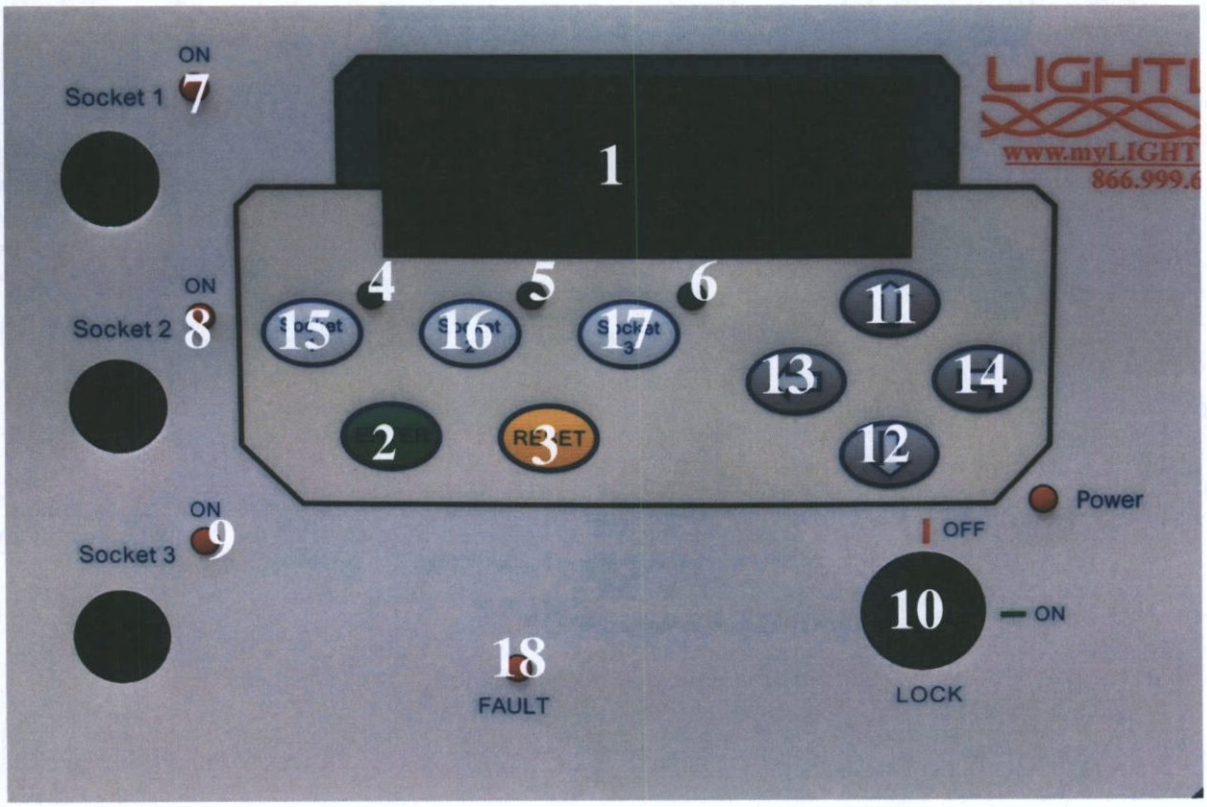
Control Unit Membrane Index

MEMBRANE CONTROL SCREEN



1. LCD Display
2. Enter Button
3. Reset Button
4. Socket 1 Display Status Button
5. Socket 2 Display Status Button
6. Socket 3 Display Status Button
7. Socket 1 and Socket 1 Active Indicator
8. Socket 2 and Socket 2 Active Indicator
9. Socket 3 and Socket 3 Active Indicator
10. LOCK
11. Up Arrow
12. Down Arrow
13. Left Arrow
14. Right Arrow
15. Socket 1 Button
16. Socket 2 Button
17. Socket 3 Button
18. Fault Indicator

Please call us toll free at (866) 999 - 6954 Monday – Friday MST from 8:00 – 5:00 so we may address any questions or concerns you have with regard to this manual, protocols, usage, etc.

Once again, thank you for choosing LIGHTWAVE™.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment #2

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

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:	November 20, 2009

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), NEW-U (K072459).

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 Professional DELUXE is intended for prescription use to release energy in the red and blue region of the spectrum to treat dermatological conditions specifically indicated to treat mild to moderate acne vulgaris. Accessories include red and blue LED panels.

LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the infrared 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 relaxation of muscle tissue and to temporarily increase local blood circulation where applied. Accessories include an Infrared LED panel.

LIGHTWAVE Professional Deluxe is intended for prescription use to release energy in the Red and Infrared spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles.

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DJA x00089

LED Predicates Comparison Chart & Specifications

Company	LIGHTWAVE Technologies LLC		Photo Therapeutics, Ltd.		Photo Therapeutics, Ltd.		SE or Different
Device Name	LIGHTWAVE Professional DELUXE		Omnilux Revive	Omnilux Plus	NEW-U		
Decription	LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions		LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions		LED based system that used multiple wavelengths in one system to treat multiple dermatological conditions		SE
K Number	to be assigned	to be assigned	K050216		K072459		N/A
Regulation Number	878.4810	890.5500	878.4810	890.5500	878.4810		N/A
Product Code	GEX	GEX	GEX	GEX	GEX		SE
Light Source	LED (noncoherent) Multi diode		LED (noncoherent) Multi diode		LED (noncoherent) Multi diode		SE
Spectrum (wavelength)	Red: 630 nm	Infrared: 880 nm	Red: 633 nm	Infrared: 830nm	Red: 633 nm	Infrared: 830nm	SE
Delivery	Treatment Head - LED Array		Treatment Head - LED Array		Hand Held - OTC		SE
Output Intensity	Red: 112mW/cm2	Infrared: 82mW/cm2	Red: 105mW/cm2	Infrared: 55mW/cm2			SE
Treatment Time	Up to 20 min		Up to 20 min		Up to 20 min		SE
Dose range (adjustable)	Red: 1-133.34 J/cm2	Infrared: 1-99.42 J/cm2	Red: 1-150 J/cm2	Infrared: 1-80 J/cm2	Per its 510k (K072459) substantially equivalent to K050216		SE
Bandwidth	Red: 25nm +/-5nm	Infrared 25nm +/-5nm	Red: 20 nm +/- 3 nm	Infrared: 30 nm +/- 5nm	Red: 20 nm +/- 3 nm	Infrared: 30 nm +/- 5nm	SE
Wave Form	CW & Variable		CW	CW	CW	CW	SE
Head/LED configuration	All built into one head. No changing of heads.		Change head to change wavelength. Not all built into one head.		All built into one head. No changing of heads.		SE with K072459 minor difference with K050216
Target Population	Individuals Suffering from indicated dermatological conditions		Individuals Suffering from indicated dermatological conditions		Individuals Suffering from indicated dermatological conditions		SE
Type of use	Prescription use		Prescription use		Prescription use		SE
Spot Size (Coverage Area)	Up to 1662 cm2		541.12 cm2	541.2 cm2			Different
Intended use	The LIGHTWAVE Professional DELUXE is intended for prescription use to release energy in the red and infrared region of the spectrum to treat dermatological conditions specifically indicated to treat periorbital wrinkles. As well as for topical heating for the intended purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain		The OmniLux Revive was cleared (K030426) for the use in dermatology for the treatment of superficial, benign vascular and pigmented lesions. The Omnilux Revive and Plus combination was cleared (K050216) for dermatological conditions, specifically indicated to treat periorbital wrinkles.	The Omnilux Plus was cleared (K043317) for topical heating for the intended purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain. The Omnilux Revive and Plus combination was cleared (K050216) for dermatological conditions, specifically indicated to treat periorbital wrinkles	The Omnilux New-U is intended to emit energy in the red and IR region of the spectrum, specifically indicated to reduce periorbital wrinkles.		SE
System Type	Table top/mobile workstation		Table top		Hand Held		SE
Size	58 in (H) x 24 in (W)		14 in (H) x 7 in (W)		5 in (H) x 2.5 in (W)		Different
Electrical Supply	AC 110VAC 220VAC 50/60 Hz		AC 110VAC 220VAC 50/60 Hz		AC 90-250VAC 50/60 Hz to DC		SE
Weight	84 lbs.		26 lbs		2.9 oz		Different

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 3