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

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 30, 2016

In Light Wellness Systems, Inc.
% Mr. Fred Ma
President And CEO
Medical Quality International, LLC
7195 Longview Drive
Cleveland, Ohio 44139

Re: K153389
Trade/Device Name: Elysiom Polychromatic LED Light Therapy System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: November 18, 2015
Received: November 23, 2015

Dear Mr. Ma:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K153389

Device Name
ElysiomTM Polychromatic LED Light Therapy System, In Light Wellness Systems, Inc.

Indications for Use *(Describe)*
To: 1) temporarily relieve minor pain, stiffness and muscle spasms; and
2) temporarily increase the local blood circulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 6.0 510(k) Summary

### Submission Application and Correspondence

**Name of Device:** Elysiom™ Polychromatic LED Light Therapy (PLLT) System, In Light Wellness Systems, Inc.

**Trade/Proprietary/Model Name**: Elysiom™ Polychromatic LED Light Therapy (PLLT) System (Elysiom™)

Common or Usual Name: LED Light Therapy Device

Classification Names: Physical Medicine Therapeutic Devices

**Table 1. Devices to Which New Device is Substantially Equivalent**

| Company | Device | K Number |
|---|---|---|
| Bioremedi Therapeutic Systems, Inc. | HealthLight™ System | K101894 |

### Device Description

Elysiom™ Polychromatic LED Light Therapy (PLLT) System is a pulsed light emitting diode (LED) device providing a temporary increase in local circulation and temporary relief of minor pain. The LED lights provide gentle warmth. Elysiom™ uses a unique timed sequence of emissions, known as pulses, to create an environment in which change occurs regularly and rapidly.

### Intended Use of the Device

1. To provide LED (light-emitting diode) light associated gentle warmth (limited temperature elevation) therapy to temporarily relieve minor pain, stiffness and muscle spasms; and
2. To temporarily increase the local blood circulation.

**Table 2. Summary of Characteristics of the Device Compared to the Predicate**

| **Product Name** | HealthLight™ System | Elysiom™ |
|---|---|---|
| **Method Of Use** | Ready to Use | Ready to Use |
| **US FDA Classification Regulation Applied** | CFR 21<br>Part 890.5500: Physical Medicine Therapeutic Devices, Lamp, Infrared, Therapeutic Heating | CFR 21<br>Part 890.5500: Physical Medicine Therapeutic Devices, Lamp, Infrared, Therapeutic Heating |
| **Device Code** | ILY | ILY |
| **Claim** | Symptomatic Relief | Symptomatic Relief |
| **Area of Use** | All body parts | All body parts |
| **Intended use** | Minor pain, stiffness, muscle spasm and impaired circulation | Minor pain, stiffness, muscle spasm and impaired circulation |
| **Type of Product** | Topical Use Device | Topical Use Device |
| **Presentation** | LED Pads and controllers | LED Pads and controllers |
| **Output Power Increments** | 12v DC | 12v DC |
| **Output Port** | 5 Pin Din Jack | 5 Pin Din Jack |
| **Power Requirements** | 100-240 VAC | 100-240 VAC |
| **Increments of Power** | 10.4-12 VDC | 10.4-12 VDC |
| **Energy of Power** | .5-5 Amps | .5-5 Amps |
| **Beam Diameter** | 5mm | 5mm |
| **Number of LEDs** | Varies per application (50-132) | Varies per application (50-264) |
| **Output of Blue LED** | 430nm-520nm | 430nm-520nm |
| **Output of Red LED** | 600nm-660nm | 600nm-660nm |
| **Output of IR LED** | 750nm-910nm | 750nm-910nm |
| **Pattern of LED** | Red/Blue alternating IR LEDs | Red/Blue alternating IR LEDs |
| **Configuration of LEDs** | Varies per application | Varies per application |
| **Wave Length** | 475nm, 640nm, 880nm | 430nm-880nm |
| **Duty Cycle** | 50.00% | 30.00-50.00% |
| **Controls** | Push button | Push button |
| **Cooling Method** | Resistor current limiter in each row of LEDs | Resistor current limiter in each row of LEDs |
| **Accessories** | Power supply, goggles, sterile sleeves | Power supply, goggles, sterile sleeves |
| **Safety Features** | Timer, fuses to prevent shorting of pads | Timer, fuses to prevent shorting of pads |

| | | |
|---|---|---|
| **Audio Warning Signal** | Time out beep | Time out beep |
| **Recommended distance from patient** | Contact skin | Contact skin |
| **Timer Modes** | 5, 10, 15, 20, 25, 30 minutes | 20 minutes |

**10. Substantial Equivalence Comparison：**

HealthLight and Elysiom™ are both pulsed infrared devices using a separate controller to power flexible pads attached by a cable. HealthLight and Elysiom™ contain an array of light emitting diodes from the same LED supplier. HealthLight and Elysiom™ controllers are designed to power more than one pad at a time. HealthLight and Elysiom™ are powered by power supplies converting power to 12VDC. HealthLight and Elysiom™ both operate with a microprocessor, a timer and an auto shut-off feature. HealthLight and Elysiom™ both have designs to allow the controller to fail in the SAFE MODE, i.e. power down completely and shut off. HealthLight and Elysiom™ both use 5 pin DIN plugs that are removable from the device, as commonly is the case for electronic devices.

HealthLight offers a two, three or four port controller configurations while Elysiom™ offers a two and six port configurations. HealthLight offers seven flexible light therapy pads to use in combination with the controller, while Elysiom™ offers nine.

The differences identified above do not adversely impact the safety and effectiveness of the In Light Wellness Systems Elysiom™ device.

As a conclusion, the Elysiom™ PLLT System Device is substantially equivalent to the predicate devices, i.e. the BioRemedi HealthLight System, (K101894).

**Non-Clinical Performance Tests:**

**14. Software verification and validation:**

Software was verified and validated by a third-party professional organization (Business & Decision, Hosting and Consulting Services). The actual results simply using Pass/Fail standards were utilized for the evaluation and they demonstrated as:

2/Port Reconciliation –All Actual Results matched the Expected Results. There were no deviations/failures. All tests passed indicating all 2/Port software requirements were met.

6/Port Reconciliation –All Actual Results matched the Expected Results. There were no deviations/failures. All tests passed indicating all 2/Port software requirements were met.

**15. Electromagnetic Compatibility and Electrical Safety (IEC 60601-1 and IEC 60601-1-2)**

ElysiomTM Polychromatic LED Light Therapy (PLLT) System has tested for IEC standards tests following FDA requirements and International Electronic Commission standards for Electronic Compatibility (IEC 6060-1-2) and Electronic Safety (IEC 6060-1-1, 3rd Edition/IEC 62471:2008 for Photobiological Safety of Lamps and Lamp System) by UL, LLC the one of most creditable world class Underwriters Laboratories located in Research Triangle Park, North Carolina (UL LLC, 12 Laboratory Drive Research Triangle Park, NC 27709 USA). The test results demonstrated that both 2/Ports and 6/Ports ElysiomTM Polychromatic LED Light Therapy (PLLT) System met IEC Electronic Safety and Electromagnetic Compatibility criteria as Polychromatic LED Light Therapy (PLLT) device coded under ILY by the US FDA, i.e. IEC 6060-1-1/IEC62471:2008 and IEC6060-1-2, 3rd Edition; while the risks for the device are extremely low and can always be mitigated.