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

October 6, 2015

Wellquest International Incorporated
% Ms. Carrie Hetrick
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K150554
Trade/Device Name: NuBrilliance Light Pain Therapy
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Dated: August 27, 2015
Received: August 28, 2015

Dear Ms. Hetrick:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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" (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/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,

Joshua C. Nipper -S

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)*
K150554

Device Name
NuBrilliance Light Pain Therapy

Indications for Use *(Describe)*
The Nu Brilliance Light Pain Therapy system is an Over-The-Counter handheld device intended for the relaxation of muscles and relief of muscle spasms; temporary relief of minor muscle and joint aches, pains, and stiffness; temporary relief of minor pain and stiffness associated with arthritis; and to temporarily increase 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary
for
NuBrilliance Light Pain Therapy
K150554

1. Submission Sponsor

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Contact: Ms. Yveth Kan

2. Submission Correspondent

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Contact: Carrie Hetrick, Senior Consultant, RA
Email: project.management@emergogroup.com

3. Date Prepared

October 5, 2015

4. Device Identification

Trade/Proprietary Name:	NuBrilliance Light Pain Therapy
Common/Usual Name:	Infrared lamp
Classification Name:	Infrared lamp
Classification Regulation:	21 CFR § 890.5500
Product Code:	ILY
Device Class:	Class II
Classification Panel:	Physical Medicine

5. Legally Marketed Predicate Device(s)

LED Technologies, LLC DPL™ Therapy System (K081570)

6. Device Description

The NuBrilliance Light Pain Therapy device is a lightweight, light emitting diode (LED) device that emits light energy. The NuBrilliance Light Pain Therapy device is an Over-The-Counter

(OTC), hand held, ergonomically designed pain relief device that uses the infrared lamp for therapeutic heating. The head consists of four (#4) visible diodes (red lights) in the 625 nm (±5%) spectrum, and (#56) fifty-six infrared diodes (purple lights) in the 940 nm (±5%) spectrum that are used in combination for therapeutic heating. It delivers infrared light to the skin resulting in a safe elevation of the skin temperature for therapeutic effects. The handle of the device contains the electronics of the device including a fan for cooling and an automatic shut-off safety feature. Treatment is controlled by the operator. There are no user settings or adjustments.

7. Indication for Use Statement

The NuBrilliance Light Pain Therapy system is an Over-The-Counter handheld device intended for the relaxation of muscles and relief of muscle spasms; temporary relief of minor muscle and joint aches, pains, and stiffness; temporary relief of minor pain and stiffness associated with arthritis; and to temporarily increase local blood circulation.

8. Substantial Equivalence Discussion

The Wellquest NuBrilliance Light Pain Therapy device utilizes the same technological characteristics and has the same intended use as the K081570 predicate device. The K081570 device emits energy from light-emitting diodes (LED)s with wavelengths of 660 nm and 880 nm. The NuBrilliance Light Pain Therapy device emit energy from light-emitting diodes (LED)s with wavelengths of 625 nm and 940 nm. Both devices provide similar irradiance output to the treatment area. The desired therapeutic effects from both devices are generated by their emissions creating a local increased temperature in the area being treated. Differences between the NuBrilliance Light Pain Therapy device and the predicate do not raise new types of questions regarding the safety and effectiveness when used for the above indications for use.

9. Non-Clinical Performance Data

The device has been tested for applicable safety requirements. The NuBrilliance Light Pain Therapy complies with the applicable voluntary standards for biocompatibility. As part of demonstrating safety and effectiveness of NuBrilliance Light Pain Therapy and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Wellquest International, Inc. completed a number of tests. The NuBrilliance Light Pain Therapy meets all the requirements for the overall design, biocompatibility, and electrical safety confirm that the output meets the design inputs and specifications. The NuBrilliance Light Pain Therapy passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the differences, between the NuBrilliance Light Pain Therapy device and the predicate device listed above, do not raise new types of questions regarding safety and effectiveness. Further, the NuBrilliance Light Pain Therapy device utilizes the same type of technology as the predicate device. The NuBrilliance Light Pain Therapy, as designed and manufactured, is determined to be substantially equivalent to the above-listed predicate device.