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

July 26, 2016

USA Laser Biotech Inc.
% Joyce M. Heinrich
President
Texas Applied Biomedical Services, Inc.
1201 Cullen Boulevard, #A
Houston, Texas 77047

Re: K161198
Trade/Device Name: Lumix Ultra 1, Lumix Ultra 2, Lumix Ultra 3
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: April 28, 2016
Received: April 28, 2016

Dear Ms. Heinrich:

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 and Part 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" (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 Post-market 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,

Christopher J. Ronk -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)*
K161198

Device Name
LUMIX ULTRA 1 IR Lamp System; LUMIX ULTRA 2 IR Lamp System; LUMIX ULTRA 3 IR Lamp System

Indications for Use *(Describe)*
The LUMIX ULTRA IR Lamp Systems are intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

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.

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510(k) Summary (as per 21 CFR 807.92)

I. GENERAL INFORMATION Device Generic Name:

Infrared Therapeutic Heat Lamp

Trade Name:

LUMIX ULTRA 1 IR Lamp System LUMIX ULTRA 2 IR Lamp System LUMIX ULTRA 3 IR Lamp System

Device Classification: Class II, Performance Standards
21CFR Part 890.5500 – Infrared Lamp

Product Code: ILY

Applicant Name and Address:

USA Laser Biotech Inc.
9210 Forest Hill Avenue
Richmond, VA 23235 USA
Telephone: 877 / 423-6169

510(k) Number: K161198

II. Device Description

The LUMIX ULTRA IR Lamp Systems are intended for use as therapeutic heat lamps. The Systems are non-invasive devices that emit light energy to the skin-surface of the human body for the purpose of causing the therapeutic elevation of tissue temperature.

The LUMIX ULTRA IR Lamp Systems deliver visible and invisible laser light beams at wavelengths between 650 and 1064 nm using gallium arsenide (GaAs) diode sources. The laser light beam is carried to the focusing lens on the handpiece probe by quartz optical fibers. The tissue to be treated is illuminated by a non-therapeutic red laser guide light with 3 mW of power. The Systems consist of 2 main hardware sub-systems: 1) the control console and 2) the treatment handpiece probe with its connecting cable.

The control consoles are made of standard medical PVC material and are designed to be placed on a desktop or table in the vicinity of the patient to be treated. The console houses the user interface, which is a pressure activated membrane and an LCD display.

The treatment probes are made of standard medical grade PVC. The laser energy for heat treatment is delivered to the treatment probe via fiberoptic cables. The probes contain a protective lens at the aperture, which is made of glass suitable for medical applications.

III. Indications For Use

The LUMIX ULTRA IR Lamp Systems are intended to emit energy in the visible and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness,

minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and/or the temporary relaxation of muscle.

IV. Predicate Devices

The LUMIX ULTRA IR Lamp Systems are substantially equivalent to other therapeutic heat lamps that are currently in commercial distribution. These predicate devices include, but are not limited to:

1. USA Laser Biotech Inc. LUMIX 3 Series Infrared Heat Lamp Therapy Systems (K132016),
2. USA Laser Biotech Inc. NEXUS Series IR Heat Lamp Systems (K101893),
3. CYNOSURE 1064nm Diode Laser (K123971), and
4. ELTECH s.r.l. K-Laser Cube 1, K-Laser Cube 2, K-Laser Cube 3, K-Laser Cube 4 (K120604).

V. Summary of the Technical Characteristics of the LUMIX ULTRA System as Related to the Referenced Predicate Devices

The LUMIX ULTRA IR Lamp Systems and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VI. Testing

Testing of the LUMIX ULTRA Systems includes functional performance testing and electrical safety testing. The Systems are manufactured to comply with the following international standards:

IEC 60601-1:2006 – Ed. 3	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60825-1:2014 – Ed. 2	Safety of Laser Products – Part 1: Classification of laser devices and requirements
IEC 60601-1-2:2010 – Ed. 3	Medical Electrical Equipment – Part 1-2: Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2013 – Ed. 3.1	Medical Electrical Equipment – Part 1-6: Collateral Standard: Usability
IEC 60601-2-22:2012 – Ed. 3.1	Medical Electrical Equipment – Part 2-22: Particular requirements for basic and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 63204:2006	Software for Medical Devices: Software life cycle processes
ISO 14971:2012 – Ed. 2	Risk Management to Medical Devices

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the LUMIX ULTRA IR Lamp Systems have the same intended uses, with similar functional and performance characteristics. The LUMIX ULTRA IR Lamp Systems are designed to comply with applicable performance standards promulgated by the U.S. Food and Drug Administration. These Systems perform as intended and do not raise any new safety or efficacy issues.