510k SUMMARY [as per 21 CFR 807.92(b) (1)]

FEB 17 2011

I. GENERAL INFORMATION

Device Generic Name: Infrared Lamp

Trade Name: Nexus 7W Lite IR Lamp System
Nexus 10W Lite IR Lamp System
Nexus 30W Pro IR Lamp System
Nexus 60W 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: K101893

II. Device Description

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

The Nexus Series IR Lamp Systems deliver an invisible laser light beam in the infrared spectrum at wavelengths of 810 and 980 nm using a gallium aluminum arsenide (GaAlAs) source. 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. 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 place 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 focusing lens at the aperture, which is made of

glass suitable for medical applications.

III. Indications For Use

The Nexus Series 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 Nexus Series IR Lamp Systems are substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include, but are not limited to, the USA Laser Biotech Inc. Nexus XPulse IR Heat Lamp Systems (K091726), the LUMINA 1600 Infrared Heat Lamp Therapy System (K052814), and ICL 60 Plus HFPL System (Models 40, 100, 250) K042256

V. Summary of the Technical Characteristics of the Nexus IR Lamp Systems as Related to the Referenced Predicate Devices.

The Nexus Series 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 Systems include functional performance testing and electrical safety testing. The Systems are manufactured to comply with the following international standards:

EN 60601-1:2001	Medical Electrical Equipment, Part 1, General Requirements for Safety
EN 60601-1-2:2001	Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility
ISO 14971	Medical Devices: Application of Risk Management

The Nexus Series IR Lamp Systems are capable of achieving therapeutic temperature range of 40 – 45 degrees centigrade as accepted by the FDA. An increase in topical heating of the tissue level by at least 5 decrees centigrade was reached within one (1) minute as demonstrated in the bench testing that was conducted on each handheld probe. The therapeutic temperature range was maintained for the 10 minute testing time. The temperatures versus time measurements were conducted on 3 subjects at 2 physical locations, i.e., shoulder, neck, knee or lower back areas. On an average, the pre-exposed topical skin temperature ranged from 30 to 32 degrees centigrade. The topical temperature during exposure following brief stabilization time ranged from 41 to 43 degrees centigrade. These data demonstrate the System meets the generally accepted topical temperature range for therapeutic heat of 40 – 45 degrees centigrade during the recommended treatment time of 10 minutes.

VII. Conclusions

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

USA Laser Biotech Inc.
% Texas Applied Biomedical Services
Ms. M. Joyce Heinrich
12101 Cullen Boulevard, Suite A
Houston, Texas 77047

FEB 17 2011

Re: K101893
Trade/Device Name: Nexus BioWave 7W Lite IR Lamp System
Nexus BioWave 10W Lite IR Lamp System
Nexus BioWave 30W Pro IR Lamp System
Nexus BioWave 60W Pro IR Lamp System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: December 31, 2010
Received: January 14, 2011

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); 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

7.0 Indications for Use Statement

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Indications for Use Statement

510(k) Number (if known): Pending

Device Name:

Nexus BioWave 7W Lite IR Lamp System
Nexus BioWave 10W Lite IR Lamp System
Nexus BioWave 30W Pro IR Lamp System
Nexus BioWave 60W Pro IR Lamp System

Indications for Use:

The Nexus BioWave Series IR Lamp Systems are intended to emit 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 and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

Prescription Use: X **AND/OR Over the Counter Use: _____**
(Part 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 (ODpE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101893