

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

**JUN 0 2 2014**

**I. GENERAL INFORMATION**

**Device Generic Name:** Infrared Low Level Laser System

**Trade Name:** Lumix 3 100W Plus and Lumix 3  
250W Ultra IR Laser Systems

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

**Product Code:** ILY

**Applicant Name and Address:** USA Laser Biotech, Inc.  
9210 Forrest Hill Avenue  
Richmond, VA 23235  
Telephone: 804 / 377-2234

**510(k) Number:** K132016

**Device Description:**

Lumix 3 100W Plus and Lumix 3 250W Ultra IR Laser Systems are laser therapy devices for applications suitable to be used in an ambulatory setting and under the care of a licensed healthcare provider. In particular the device works by providing infrared energy to elevate tissue temperature.

The Lumix 3 series laser therapy heat lamp heat devices deliver visible and invisible laser light at the wavelength of 910 nm (pulsed infrared), 808nm (continuous and interrupted infrared) and 650nm (continuous red visible). The pulsed laser sources used are of diodic type for pulsed working mode; the continuous laser sources used are of diodic type for continuous and frequenced working mode.

The laser light beam produced by the diode is carried to the focusing lens optic fibers with very low attenuation and high mechanical strength. The laser light, produced by the different sources, is emitted in a single bright beam, which at the optical unit output has a diameter equal to at 20mm. The flexible arm can be oriented by the user at will to heat-treat the required tissue area.

The optical unit contains a focusing lens with a high transmission coefficient used to focus the light beam carried by the optical fibers on the tissue to be treated. In order to identify precisely the tissue area to be irradiated, it is important to have a guide light available (650nm red) with a beam collimated with the laser light beam. The guide light allows one to visualize the target site clearly. The red guide light has no therapeutic value.

**Technical Observations:**

The pulsed and superpulsed laser emission consists of a sequence of pulses lasting about 200 ns repeated at a pulse rate varying from 1 Hz to 100,000 Hz. (cycles per second).

The laser emission from the 808nm continuous wave diode can be in a continuous emission or a modulated (interrupted) mode. In the modulated mode the pulses are emitted at varying pulse rates from 1 Hz to 100,000 Hz (cycles per second).

By setting the modulation DUTY-CYCLE it is possible to change the lighting time as to the interruption one into the 5 seconds period:

<b>DUTY-CYCLE</b>	<b>TRAIN IMPULSES LENGTH</b>	<b>PAUSE DURATION</b>
20	1 second	4 seconds
50	2.5 seconds	2.5 seconds
80	4 seconds	1 second

The amount of energy at the optical system output point can be calculated by applying the following formula:

$$E(J)_{total} = E(j)_{pw910nm} + E(j)_{cw808nm}$$

**Where:**

$$E(j)_{pw910nm} = \text{Peak power (W)} \times \text{diodes number} \times \text{impulse width (sec)} \times \text{modulation} \times \text{treatment time (sec)}$$

$$E(j)_{pw910nm} = \text{Peak power (W)} \times \text{Coefficient} \times \text{modulation} \times \text{treatment time (sec)}$$

**Where Coefficient is:**

- 1 if the diode is on in CW modality
- 0.5 if the diode is on in pulsed modality

**III. Indications for Use:**

The Lumix 3 100W Plus and Lumix 3 250W Ultra IR Laser 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.

**IV. Predicate Devices:**

The Lumix 3 100W Plus and Lumix 3 250W Ultra are substantially equivalent to other infrared therapeutic devices that are currently in commercial distribution. Following is a list of the predicate devices cleared by the FDA via 510K Notification process.

<b>510(k) Number</b>	<b>Predicate Device Name</b>	<b>Manufacturer</b>
K042256	ICL 60 Plus HFPL System	USA Laser Biotech, Inc.

**V. Summary of the Technical Characteristics of the Lumix 3 Systems as Related to the Referenced Predicate Devices:**

The Lumix 3 100W Plus System is the same technologically and functionally as the ICL 60, Model 100 and the Lumix 3 250W Ultra is the same as the ICL 60, Model 250. These predicate devices were cleared by the 510K process (K042256). The Lumix 3 Systems have the same intended use as the ICL 60 Systems. These devices utilize infrared laser diodes, SLD diodes and visible LED diodes for the purpose of providing adjunctive use in pain therapy.

**VI. Bench Testing:**

Electrical safety and functional performance testing were conducted on the Lumix 3 Systems demonstrating that the devices are compliant with FDA recognized consensus standards. These standards include the following international standards:

STANDARD	DESCRIPTION
EN 60601-1:2007	Medical Electrical Equipment, Part 1, General Requirements for Safety
EN 60601-1-2:2007	Medical Electrical Equipment, General Requirement for Safety, Electromagnetic Compatibility
EN 60601-2-22	Medical Electrical Equipment, Part 2, Particular Requirements for the safety of diagnostic and therapeutic laser equipment
EN 60601-1-4:1996	Programmable electrical medical systems
ISO 13485:2003	Medical Device Quality Management System
Council Directive 93/42/EEC	EC Declaration of Conformity

**VII. Non-Clinical Testing:**

The use of light energy to generate heat for therapeutic use has been well documented and is generally accepted alternative treatment modality for the temporary relief of pain and tissue repair.

The Lumix 3 100W Plus and Lumix 3 250W Ultra IR Laser Systems are capable of achieving therapeutic heat 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° centigrade was reached within one (1) minute demonstrated in the clinical testing conducted. The therapeutic temperature range was maintained for at least ten (10) minutes.

The temperature versus time measurements was conducted on 8 subjects at various physical locations, i.e., leg, neck, back and shoulder. The pre-exposed topical skin temperature ranged from 36 to 39 degrees centigrade. These data from the Lumix 3 100W Plus and Lumix 3 250W Ultra IR Laser Systems demonstrates that they meet the generally accepted topical temperature range for therapeutic heat of 40 – 45 degrees centigrade during the recommended treatment time of 10 minutes.

**VIII. Conclusions:**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device may have the same intended use and different technological characteristics if they can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regards its safety and effectiveness as compared to the predicate device.

The Lumix 3 100W Plus and Lumix 3 250W Ultra Systems have the same intended uses, and technical, functional and performance characteristics as the predicate devices listed above. The Lumix 3 100W Plus and Lumix 3 250W Ultra IR Laser Systems are designed to comply with applicable performance standards promulgated by Federal Food and Drug Administration.



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

June 2, 2014

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

Re: K132016

Trade/Device Name: Lumix 3 100W Plus and Lumix 250W Ultra IR Laser Systems  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared lamp  
Regulatory Class: Class II  
Product Code: ILY  
Dated: May 8, 2014  
Received: May 14, 2014

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 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,

**David Krause -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

**Indications for Use**

510(k) Number (if known)  
K132016

Device Name

Lumix 3 100W Plus and Lumix 3 250W Ultra IR Laser Systems

Indications for Use (Describe)

The Lumix 3 100W Plus and Lumix 3 250W Ultra 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.

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)

Neil R Ogden -S

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