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

January 7, 2015

Applied BioPhotonics, Ltd.
% Ms. Roshana Ahmed
OptumInsight (Canada) Incorporated
4 Innovation Drive
Dundas, Ontario L9H 7P3
CANADA

Re: K142256
Trade/Device Name: Applied BioPhotonics® Phototherapy System ABPT1003
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp, Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ILY
Dated: December 17, 2014
Received: December 18, 2014

Dear Ms. Ahmed:

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

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)*
K142256

Device Name
Applied BioPhotonics® Phototherapy System ABPT1003

Indications for Use *(Describe)*
Applied BioPhotonics® Phototherapy System ABPT1003 is intended to provide phototherapeutic light to the body. The device emits:

- Red and infrared light to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, sprains, strains, and muscle spasm, as well as back, neck and shoulder pain; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Preparation Date: December 16, 2014

Submitter:
Address: Applied BioPhotonics Ltd.
15th Floor, Far East Consortium Building 121 Des Voeux Road, Central, Hong Kong, China SAR
Phone: +886-3-621-8538
Fax: +886-3-668-3089
Contact: Eric Hsieh
(erichsieh@appliedbiophotonics.com)

Identification of the Device:

Proprietary/ Trade name:	Applied BioPhotonics® Phototherapy System ABPT1003
Classification Name:	Lamp, Infrared, Therapeutic Heating Powered Laser Surgical Instrument
Device Classification:	II
Regulation Number:	890.5500 878.4810
Panel:	Physical Medicine General & Plastic Surgery
Product Code:	ILY GEX

Predicate Devices

Substantial equivalence is claimed to the following devices as related to intended use, design, and technological characteristics:

- IllumiMed™, PhotoActif, LLC, K060792
- LIGHTWAVE Professional Deluxe, LIGHTWAVE Technologies LLC, K082586
- LumiWave 1X4 Infrared Therapy Device, BioCare Systems, Inc., K051816
- HealthLight™ MicroController, MiniPro, ProNeuroLight and Pro Unit, BioRemedi Therapeutic Systems, Inc., K101894

Description of the Device

The Applied BioPhotonics® Phototherapy System ABPT1003 is a light therapy device using specific wavelengths of polychromatic energy produced by super-luminous light emitting diodes (LEDs) to treat a variety of skin and body conditions.

The device can be described as a Class II Low Level Light treatment process employing the application of light and heat, which penetrates the skin surface to the underlying tissues, triggering normal cellular functions. This technology is commonly referred to as photobiostimulation, light emitting diode therapy (LEDT), LLLT, or LED's. The application of LED's to tissue is non-invasive.

Using patent pending and proprietary techniques and computational processes, the Applied BioPhotonics® Phototherapy System ABPT1003 is composed of:

- Proprietary hardware (i.e. ABLM1002 LightMachine)
- LightOS software (running in the LightMachine)
- LightPad sets (ABLP103) comprising flexible, aseptic, polymeric LED pads
- Cables (for connecting LightPads and LightMachines)

The IR and red spectrum emitted from LEDs in the ABLP103 LightPad sets is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, sprains, strains, and muscle spasm, as well as back, neck and shoulder pain; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

The LightMachine control panel displays to the operator what treatment is being performed and provides the user with a choice of driving one or two LightPad sets with any chosen treatment protocol.

The software component of the device controls the user's selection of specific treatment protocols on the LightMachine's control panel. The treatment may be set manually by entering LED-operating conditions (i.e. wavelength, duration, and pulse frequency) or by selecting preset treatment protocols. The software is revision-controlled and can be upgraded by the manufacturer.

This is a prescription use only device. The labeling, instructions and user operations are designed for health care professionals.

Intended Use/Indications for Use

Applied BioPhotonics® Phototherapy System ABPT1003 is intended to provide phototherapeutic light to the body. The device emits:

- Red and infrared light to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, sprains, strains, and muscle spasm, as well as back, neck and shoulder pain; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Technological Characteristics

The Applied BioPhotonics® Phototherapy System ABPT1003 employs pulsed LED of the same wavelengths as the predicate devices for the same indicated uses, yet provides the user with a greater degree of independent control of each set of LightPads, as well as greater flexibility in setting, sequencing, and monitoring the LED pulse conditions (wavelength, duration, pulse frequency) before and during treatments.

Applied BioPhotonics® Phototherapy System ABPT1003 affords added safety over the predicate devices with an integral hardware safety timer, AC socket with inline fuse and mechanical off switch, universal input power supply (capable of safely operating at 120VAC or 240VAC inputs).

Based on the comparison table below, the proposed device is substantially equivalent to the predicate devices in intended use, safety and performance claims.

----------This space intentionally left blank----------

	Proposed device	**Predicate device**	**Predicate device**	**Predicate device**	**Predicate device**
Item	Applied BioPhotonics® Phototherapy System ABPT1003	illumiMed™	LIGHTWAVE Professional Deluxe	LumiWave 1X4 Infrared Therapy Device	HealthLight™ MicroController, MiniPro, ProNeuroLight and Pro Unit
510(k) Number		K060792	K082586	K051816	K101894
LED	Interchangeable Pads	Interchangeable Pads & Wands	Interchangeable Panels	LED Strap (Faceplate)	Interchangeable Panels
Power	120–230VAC, switched, fused	120VAC, switched	120VAC	120VAC	120VAC
Software	Upgradeable, Revision Controlled	Upgradable	Fixed	Fixed	Fixed
User Control	LCD Panel, Select Treatment (Program), Preset or Manual LED Settings, Automatic LED Sequencing Capable, Independent Control and Monitoring of Each Set of LightPads	Control Panel, Select Protocol (Program), Preset LED Settings, Automatic LED Sequencing Capable	LCD & keyboard, Select Function, Preset LED Settings	High / Low Select, Preset LED Settings	Control Panel, Select Protocol (Program), Preset LED Settings, Automatic LED Sequencing Capable
LED Pulse Frequencies	Multiple	Multiple	Multiple	Single	Multiple
LED Wavelengths	630nm red 850nm NIR	430nm blue 660nm red 940nm NIR	N/S blue 630nm red 830nm NIR	880nm NIR	430nm blue 630nm red 880nm NIR
Safety Timer	Yes	No	No	No	Yes
Pad Surface	Flexible Pads – Non-Porous	Flexible Pads – Porous	Rigid Pad – Non-Porous Flexible Pads - Porous	Rigid Pad – Non-Porous	Flexible Pads – Very Porous

Non-Clinical Testing

A series of studies were performed to assess the safety and effectiveness of the Applied BioPhotonics® Phototherapy System ABPT1003 including:

- Electromagnetic compatibility tests
- Electrical safety tests
- Software verification and validation

Testing was done in compliance with standards including, but not limited to, the following:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
- IEC 62471 Photobiological Safety of Lamps and Lamp Systems
- IEC 62304 Medical device software – Software life cycle processes

All laboratory tests and measurements were performed by an independent test lab certified to make such assessments. All the test results demonstrate that Applied BioPhotonics® Phototherapy System ABPT1003 meets the requirements of its pre-defined acceptance criteria and intended uses.

Clinical Testing

Clinical test data is not required to support the safety and effectiveness of this device.

Conclusion

The Applied BioPhotonics® Phototherapy System ABPT1003 has similar intended use, similar fundamental scientific technology, and similar technological characteristics with the predicate devices. Analysis of performance data including bench and safety testing data demonstrates that the Applied BioPhotonics® Phototherapy System ABPT1003 is as safe and effective as, and is therefore, substantially equivalent to, the predicate devices.