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 7, 2017

Crystal Medtech, LLC
Nelson Marquina
Manager, Regulatory Affairs
4704 Bayberry Street
Schofield, Wisconsin 54476

Re: K171087
Trade/Device Name: AXON IR Heat Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: April 8, 2017
Received: April 12, 2017

Dear Nelson Marquina:

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" (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 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,

Jennifer R. Stevenson -S3

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)*
K171087

Device Name
AXON IR Heat Lamp

Indications for Use *(Describe)*
The AXON IR Heat Lamp System is 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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008_510(k) Summary (as per 21 CFR 807.92)

I. GENERAL INFORMATION

Device Generic Name: Infrared Therapeutic Heat Lamp

Trade Name:

AXON IR Heat Lamp System

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

Product Code: ILY

Applicant Name and Address:

Crystal MedTech, LLC
4704 Bayberry Street
Schofield, WI 54476
USA
Telephone: 715 / 843-0325

510(k) Number: Pending

II. Device Description

The AXON IR Heat Lamp System is intended for use as a therapeutic heat lamp. The System is a non-invasive device that emits light energy to the skin-surface of the human body for the purpose of causing the therapeutic elevation of tissue temperature.

The AXON IR Heat Lamp System deliver invisible laser light beams at 810 and 915 nm wavelengths 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 green laser guide light with 3 mW of power. The System consists 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 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 AXON IR Heat Lamp System is 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 AXON IR Heat Lamp System is 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 System (K101893),
3. 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 AXON System as Related to the Referenced Predicate Devices

The AXON IR Heat Lamp System and the 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 AXON System includes electromagnetic compatibility, software validation and verification, functional performance testing, and electrical safety testing. The System is 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 60601-1-2:2007 – 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 AXON IR Heat Lamp System have the same intended uses, with similar functional and performance characteristics. The AXON IR Heat Lamp System is 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.

Table 3. Technical Characteristics and Comparison Chart

Characteristic	AXON IR Heat Lamp	LUMIX 3 Series IR Heat Lamp	NEXUS Series IR Heat Lamp	K-LASER CUBE 1, 2, 3, and 4 Heat Lamp
Manufacturer	Crystal MedTech, LLC	Fisioline S.r.l.	Wuhan Gigaa Laser Optronics Technology Co., Ltd.	ELTECH S.r.l.
510k Number	Pending	K132016	K101893	K120604
Power Supply	115/230 VAC, 6.3A power supply, single phase	115/230 VAC, 6.3A power supply, single phase	DC26V/4A. Use SINPRO MPU100-102 desktop power supply adapter	DC12V SINPRO MPU100-106 desktop power supply adapter
Heat Source	GaAs diode and red guide beam diode	GaAs diode and red guide beam diode	GaAlAs diode and red guide beam diode	GaAlAs diode and red guide beam diode
Wavelengths (nm)	810 and 915	650, 810 and 910	665, 810 and 980	660, 800, 905, and 970
Power Range of Max. Output	1 W to 20 W	4.2 W to 8.2 W	7 W to 60 W	10 W to 20 W
Laser Classification	4	4	4	4
CFR Regulation	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500
Product Code	ILY	ILY	ILY	ILY
Clearance Type	Prescription	Prescription	Prescription	Prescription
Treatment Mode	Pulsed / Continuous	Pulsed / Continuous	Pulsed / Continuous	Pulsed / Continuous
Treatment Times	Variable	Variable	Variable	Variable
Delivery System	Fiberoptic cable / handheld probe	Fiberoptic cable / handheld probe	Fiberoptic cable / handheld probe	Fiberoptic cable / handheld probe

014_Non-Clinical Performance Data

AXON IR Heat Lamp System

The AXON IR Heat Lamp System can achieve 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 degrees centigrade was reached within one (1) minute as demonstrated in the bench testing that was conducted. The therapeutic temperature range was maintained for the 10-minute testing time.

The average ambient temperature at the beginning of the testing was approximately 22 degrees centigrade. The temperatures versus time measurements were conducted on 3 subjects at 2 physical locations i.e., knee, ankle, shoulder, neck, upper and/or low back. 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 40 to 45 degrees centigrade. The average warm-up time for the devices was less than two minutes. The average time to achieve therapeutic temperature (40 – 45 degrees centigrade) was less than 2 minutes. 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. The results of these tests are summarized in Tables 4 to 6.

Table 4. Temperature versus Time for AXON IR Heat Lamp System: Subject 1

Device:	**AXON**	Spacer: 6 cm Diam: 6 cm		Spot: 28 cm^2	
Settings:	AP 810 & 915 nm combined = 4.0 W				
	t = 600 s		Warming Time = 2 minutes		
Subject:	Gender: male	Age: 62	Ethnicity: Hispanic	L1: back	L2: ankle

Room Temperature: start = 22.2 °C **Room Temperature: end =** 22.3 °C

Location1:	Upper Back	**Location2:**	Ankle
Time (min)	**Temp (°C)**	**Time (min)**	**Temp (°C)**
initial	31.0	initial	29.0
1	40.0	1	40.0
2	41.0	2	41.0
3	42.0	3	41.0
4	42.0	4	41.0
5	43.0	5	42.0
6	43.0	6	42.0
7	43.0	7	42.0
8	44.0	8	42.0
9	44.0	9	43.0
10	45.0	10	43.0
Mean (active):	42.7	Mean (active):	41.7
St. Dev.:	1.49	St. Dev.:	0.95

Comments:

Table 5. Temperature versus Time for AXON IR Heat Lamp System: Subject 2

Device:	**AXON**	Spacer: 6 cm Diam: 6 cm		Spot: 28 cm^2	
Settings:	AP 810 & 915 nm combined = 4.0 W				
	t = 600 s		Warming Time = 2 minutes		
Subject:	Gender: female	Age: 30	Ethnicity: Black	L1: leg	L2: ankle

Room Temperature: start = 23.1 °C **Room Temperature: end =** 22.9 °C

Location1:	Leg	**Location2:**	Ankle
Time (min)	**Temp (°C)**	**Time (min)**	**Temp (°C)**
initial	30.0	initial	30.0
1	41.0	1	40.0
2	41.0	2	41.0
3	41.0	3	41.0
4	42.0	4	42.0
5	42.0	5	42.0
6	42.0	6	43.0
7	43.0	7	42.0
8	43.0	8	43.0
9	44.0	9	42.0
10	43.0	10	43.0
Mean (active):	42.2	Mean (active):	41.9
St. Dev.:	1.03	St. Dev.:	0.99

Comments:

Table 6. Temperature versus Time for AXON IR Heat Lamp System: Subject 3

Device:	**AXON**	Spacer: 6 cm	Diam: 6 cm	Spot: 28 cm^2	
Settings:	AP 810 & 915 nm combined = 4.0 W				
	t = 600 s		Warming Time = 2 minutes		
Subject:	Gender: female	Age: 37	Ethnicity: White	L1: leg	L2: shoulder

Room Temperature: start = 21.8 °C **Room Temperature: end =** 22.2 °C

Location1:	Leg	**Location2:**	Shoulder
Time (min)	**Temp (°C)**	**Time (min)**	**Temp (°C)**
initial	31.0	initial	30.0
1	41.0	1	40.0
2	42.0	2	41.0
3	42.0	3	42.0
4	42.0	4	43.0
5	43.0	5	42.0
6	44.0	6	42.0
7	43.0	7	43.0
8	43.0	8	44.0
9	44.0	9	44.0
10	45.0	10	45.0
Mean (active):	42.9	Mean (active):	42.6
St. Dev.:	1.20	St. Dev.:	1.51

Comments: