DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 3, 2014

Pro Medical Supplies Inc.
c/o Ms. Doris Dong
Shanghai CV Technology Co., Ltd.
Room 1706, No. 128 Songle Rd., Songjiang Area,
Shanghai, China 201600

Re: K140865
Trade Name: Infrared Heating Device, Model PM-750
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: July 17, 2014
Received: July 28, 2014

Dear Ms. Dong:

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,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine 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 on last page.

510(k) Number *(if known)*
K140865

Device Name
Infrared Heating Device, Model PM-750

Indications for Use *(Describe)*
The Infrared Heating Device, Model PM-750, temporarily increases local blood circulation where applied, and temporarily relieves minor muscle and joint aches and pains.

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)*

Felipe Aguel -S Date: 2014.09.03 04:54:42 -04'00'

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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K140865
Date:	July 15th, 2014
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Applicant/US importer:	Pro Medical Supplies Inc. 1800 Byberry Rd. Unit 905, Huntingdon Valley, PA 19006, USA
Manufacturer:	Shenzhen Yizekang Technologies Co., Ltd. 2nd Floor, No. 6 Factory, Hekan Road, Hekan Village, Bantian Sub-District, Longgang District, Shenzhen 518131, China
Contactor:	Doris Dong (Consultant) Shanghai CV Technology Co., Ltd. Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, China 201600 E-mail: doris_d@126.com

2. Device Description:

Proprietary Name:	Infrared Heating Device, Model PM-750
Common Name:	Infrared lamp
Classification Name:	Infrared lamp
Product Code:	ILY
Device Class:	2
Review Panel:	Physical Medicine
Regulation Number:	890.5500
Indications for use:	The Infrared Heating Device, Model PM-750, temporarily increases local blood circulation where applied, and temporarily relieves minor muscle and joint aches and pains.
Device Description:	The Infrared Heating Device, Model PM-750, is 110V AC powered, non-invasive, therapeutic medical device that provides continuous heat therapy through the use of infrared bulb. The device consists of a handle that houses the electronics and controls, and tungsten infrared bulb with light filter. The light filter is intended to be placed directly on the skin to provide topical heating. The infrared bulb is replaceable. The housing material is ABS.
Standards:	AAMI ANSI ES60601-1, IEC 60601-1-2, ISO 10993-1, ISO 10993-5, ISO 10993-10

3. Predicate Device Identification

510k Number:	K990233
Product Code:	ILY
Device Name:	ST-302 Infrarex
Manufacturer:	Skylark Device Company Limited

4. Substantial Equivalence:

Detailed comparison data is included in Section 9 of “Substantial Equivalence Discussion” of this 510(k) submission.

A. Basic technological characteristics & Specifications, New device VS. Predicate device:

Parameters		New Device	Predicate Device
1	510(k) Number:	K140865	K990233
2	Marketing clearance date:	--	Oct 27, 1999
3	Proprietary Name:	Infrared Heating Device, Model PM-750	ST-302 Infrarex
4	Manufacturer:	Shenzhen Yizekang Technologies Co., Ltd.	Skylark Device Company Limited
5	Indications for use:	The Infrared Heating Device, Model PM-750, temporarily increases local blood circulation where applied, and temporarily relieves minor muscle and joint aches and pains.	The Infrarex temporarily increases local blood circulation where applied, and temporarily relieves minor muscle and joint aches and pains.
6	Power source	110V AC/60Hz	110V AC/60Hz
7	Maximum output power	7.5W	7.5W
8	Power switch function	High/Off/Low	High/Off/Low
9	Type of heat source and number	1 tungsten infrared bulb	1 tungsten infrared bulb
10	Design Principle	FIR (far-infrared) therapy	FIR (far-infrared) therapy
11	Wavelength	7 000 nanometers	7 000 nanometers
12	Therapeutic temperature range	40-45℃	40-45℃
13	Approximate maximum skin temperature	Low Level: 40.5℃ High Level: 44.5℃	Low Level: 40.5℃ High Level: 44.5℃
14	Time to reach therapeutic temperature range	Low Level: 5~10 minutes High Level: 3~5 minutes	Low Level: 5~10 minutes High Level: 3~5 minutes
15	Recommended treatment time	Used for 15-20 minutes on target area	Used for 15-20 minutes on target area
16	Weight	200g	200g
17	Treatment area	$18cm^2$	$18cm^2$
18	Performance standards	ISO 10993-1, ISO 10993-5, ISO 10993-10, AAMI ANSI ES60601-1, IEC 60601-1-2	ISO 10993-1, ISO 10993-5, ISO 10993-10, IEC 60601-1, IEC 60601-1-2

B. Substantial Equivalence Discussion

Similarities between New device and Predicate Device:	The new device and the predicate device are produced by different manufacturers.
Differences between New device and Predicate Device:	Same intended use, design, materials, technical parameters, therapeutic parameters, and performance standards.
Conclusion: The two devices have exactly same intended use, design, materials, technical parameters, therapeutic parameters and performance standards. The new device is as safe and effective as the predicate device.	

5. Safety and Effectiveness of the device

Testing of Infrared Heating Device, Model PM-750, includes electrical safety testing and performance testing.

The device is manufactured to comply with the following international standards:

AAMI / ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

The housing material and the material of the light filter of PM-750, ABS, was tested and found to meet the biocompatibility standards of:

* ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
* ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, and
* ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

In addition, two devices were tested for heat output, with the infrared light filter contacting the skin. Temperatures were recorded every 1 minute, up to 30 minutes, using a digital temperature sensor, through 6 participants on different body part. The test results concluded that the Infrared Heating Device, Model PM-750 was able to maintain temperature above 40℃ (the desired effective temperature) at least 10~15 minutes of the 30 minutes cycle time. The tests also showed that the temperature at the sensor (skin) never exceeded a temperature of 45℃. Both devices used for this test tracked each near 100%.

The conclusion drawn from the testing is that the device is substantially equivalent to the predicate devices.