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

December 15, 2016

WS Far IR Medical Technology Co., Ltd.
Chih-wen Tsai
Product Specialist
2f, No.4, Lane 130, Minquan Rd.
Xindian Dist.
New Taipei City, 231 TW

Re: K160849
Trade/Device Name: WS™ Far-infrared Therapy Unit, Model: KP-B210
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: November 1, 2016
Received: November 14, 2016

Dear Chih-wen Tsai:

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 yours,

Michael J. Hoffmann -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 below.

510(k) Number *(if known)*
K160849

Device Name
WS(TM) Far-Infrared Therapy Unit, Model KP-B210

Indications for Use *(Describe)*
The WS(TM) Far-Infrared Therapy Unit, Model: KP-B210, may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may also help muscle spasms, minor sprains and strains.

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.

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
K160849

Type of Submission: Traditional

Date of Summary: November 1, 2016

Submitter: WS FAR IR MEDICAL TECHNOLOGY CO., LTD.
Address: 2F., No.4, Lane 130, Minquan Rd., Xindian Dist., New Taipei City 231, Taiwan (R.O.C.)
Phone: +886-2-8219-2005
Fax: +886-2-8219-2009
Contact: CHIH-WEN TSAI (info@far-infrared.com.tw)

Identification of the Device:

Proprietary/Trade name:	WS^{TM} Far-Infrared Therapy Unit, Model: KP-B210
Regulation Description:	Infrared lamp
Review Panel:	Physical Medicine
Regulation Number:	890.5500
Device Class:	II
Product Code:	ILY

Identification of the Predicate Device:

Predicate Device Name:	WS^{TM} Far-Infrared Therapy Unit, Model # TY-101 Series
Manufacturer:	WS FAR IR MEDICAL TECHNOLOGY CO., LTD.
Regulation number:	890.5500
Device Class:	II
Product Code:	ILY
510(k) Number:	K080465

Intended Use/ Indications for Use of the subject device

The WS™ Far-Infrared Therapy Unit, Model: KP-B210, may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may also help muscle spasms, minor sprains and strains.

Device Description

The WS™ Far-Infrared Therapy Unit, Model: KP-B210, is an infrared heating system which delivers 3~25 μm Far-infrared energy through Far Infrared (FIR) radiation plate. The device is a non-invasive physiology therapy device and emits topical heat to the human forearm and upper arm for therapeutic applications without direct contact. The model, KP-B210 is a single object without additional assembly which contains an emitter, a user control panel, a power switch and safety distance reminder.

Non-clinical Testing

A series of safety and performance tests were performed on the proposed device, WS™ Far-Infrared Therapy Unit, Model: KP-B210.

- Electrical safety and EMC tests
- Spectrum test
- Function certification test
  - Functional characteristics of the user panel
  - Operational characteristics of the emitter
  - Tip-over safety protection
- Usability test
- Temperature safety tests

The spectrum test demonstrates that the proposed device can emit far-infrared and the wavelength is 3 to 25 μm as intended. And the function certification test demonstrates that the proposed device can meet the functional and operational requirements and its intended use. Temperature safety testing shows that the device

would not cause any skin burns, safety concerns or fire risks. The comparison analysis has also been conducted to prove the substantial equivalence between the proposed and predicate device.

Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

Substantial Equivalence Determination

The WS™ Far-Infrared Therapy Unit, Model: KP-B210 has the same intended use, same principle of operation and similar technological characteristics with the predicate device (K080465). A series of tests were performed and demonstrated substantial equivalence between the proposed and the predicate device. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	**Subject device K160849**	**Predicate device K080465**		**Rationale**
Proprietary name	WS™ Far-Infrared Therapy Unit Model	WS™ Therapy Unit		N/A
Model No.	KP-B210	TY-101N	TY-101F	N/A
Indications for Use	The WS™ Far-Infrared Therapy Unit, Model: KP-B210, may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the	The WS™ therapy units, ty-101n and ty-101f may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporar increase in local circulation where applied and relaxation of muscles. In addition, the lamp may also help		IFU of subject device is within the scope of the predicate device

	temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may also help muscle spasms, minor sprains and strains.	muscle spasms, minor sprains, and strains, and minor muscular back pain	
Principle of Operation	Far Infrared (FIR) radiation plate included in the proposed device is composed of delicate ceramic plate (Al_2O_3), heating element (Electronic pastes), FIR emitting material (Dielectric pastes) and silver electrode (conductor pastes), and can emit energy in the infrared spectrum (3~25 μm).	FIR emitting component, composed of delicate ceramic plate, heating element, and high IR emissivity mineral mixture (such as silicon, calcium, chromium, copper, carbon etc.) to emit energy in the infrared spectrum (3~25 μm)	Different but does not adversely impact safety and effectiveness of subject device
Key component	Far Infrared (FIR) radiation plate included in the proposed device is composed of delicate ceramic plate (Al_2O_3), heating element (Electronic pastes), FIR emitting material (Dielectric pastes) and silver electrode (conductor pastes).	FIR emitting component composed of delicate ceramic plate, heating element, and high IR emissivity mineral mixture.	Different but does not adversely impact safety and effectiveness of subject device

Location	Forearm	Entire body	Different but does not adversely impact safety and effectiveness of subject device
Power setting	High, Low	High, Medium, Low	Similar
Time setting	10-90 minutes	0-90 minutes auto timer	Similar
Input power/Frequency	110V, 50/60Hz	110V, 50/60Hz	Same
Rated current	0.7A	1.4A	Different but does not adversely impact safety and effectiveness of subject device
Enclosure Leakage current	<0.05 mA	<0.05 mA	Same
Fuse	1A	2A	Different but does not adversely impact safety and effectiveness of subject device
Spectrum range	3-25 um	3-25 um	Same
Emitting Area	50mm x 100mm x 2 pcs	50mm x 100m x 4 pcs	Similar
Treatment Area	~100 cm^2	~200 cm^2	Different but does not adversely impact safety and effectiveness of subject device
Distance of radiation	15-30 cm	15-30 cm	Same
Power density of irradiated area	10-20 mW/cm^2	20-30 mW/cm^2	Different but does not adversely impact safety and effectiveness of subject device

Power consumption	<100 watts	<200 watts		Different but does not adversely impact safety and effectiveness of subject device
Temperature at heating surface	High 230 ± 15°C Low 180 ± 10°C	High 230 ± 15°C Medium 200 ± 15°C Low 180 ± 10°C		Similar
Recommended Time of radiation	20-40 mins	20-40 mins		Same
Storage environment	Temp: -15°C – 50°C RH: 10% - 90%	Temp: -15°C – 70°C RH: 10% - 90%		Same
Shipping environment	Temp: -15°C – 70°C RH: 10% - 90%	Temp: -15°C – 70°C RH: 10% - 90%		Same
Operation environment	Temp: 10°C – 30°C RH: 10% - 90%	Temp: 10°C – 40°C RH: 10% - 90%		Similar
Emitter Use Life	3000 hours	1000 – 1500 hours		Does not adversely impact safety and effectiveness of subject device
Product Shelf Life	5 years	3 years		Does not adversely impact safety and effectiveness of subject device
Size	Length: 28 cm Width: 20 cm Height: 33.5 cm	Emitter: 30 x 25 x12 cm Supporting arm: 75 x 15 x 4 cm Control Box: 26 x 25 x 20 cm Base: 60 cm diameter		Does not adversely impact safety and effectiveness of subject device
Weight	2.8 Kg/Set	13.3 Kg/set	14.0 Kg/set	Does not adversely impact safety and effectiveness of

				subject device
Cooling fan	Emitter with heat dissipating fan and temperature control sensor switch	N/A	Emitter with heat dissipating fan and temperature control sensor switch	Same

Similarity and differences

The differences between the subject device and the predicate device are configuration and several technical parameters. The subject device has undergone safety and performance tests, and the results complied with the test requests. A comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. Therefore, the difference between the subject device and the predicate device did not raise any problems of substantial equivalence. The proposed device is substantially equivalent to the predicate device in intended use, safety and performance claims.

Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that WS^{TM} Far-Infrared Therapy Unit, Model: KP-B210 is substantially equivalent to the predicate device.