March 3, 2022

Xiamen Healthpal Electronic Co.,Ltd
Henry Zhang
Manager
No.170 Siming Park Tongan District, Xiamen City,
Fujian Province, China
Xiamen, Fujian 361100
China

Re: K211850
Trade/Device Name: Air Compression Leg Massager (model: FE-7204B)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 26, 2022
Received: February 2, 2022

Dear Henry Zhang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211850

Device Name
Air Compression Leg Massager (model: FE-7204B)

Indications for Use *(Describe)*
Air compression leg massager, model:FE-7204B, is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated foot/calf and thigh in people who are in good health. The air compression leg massager simulates kneading and stroking of tissues by using air-inflatable boots.

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.

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510(k) Summary

The assigned 510(k) number is: K211850
Prepared date: January 25, 2022

Submitter Identification:

Name: Xiamen Healthpal Electronic Co., Ltd.
Address: No.170 Siming Park Tongan District, Xiamen City,
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Xiamen, Fujian 361100

Contact Person: Henry Zhang
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Name of the Device:

Trade Name: Air Compression Leg Massager (model: FE-7204B)
Classification Name: Powered Inflatable tube massager

Classification Information:

Regulation Number: 21 CFR 890.5650
Product Code: IRP
Device Class: II
Review Panel: Physical Medicine

Predicate Device Information:

Sponsor Name: Rapid Reboot Recovery Products,
LLC 1396 W 200 S Bldg 2A, Lindon, UT 84042, USA
Trade/Device Name: Rapid Reboot Compression Therapy System
510(k) Number: K182668

Device Description:

The Air Compression Leg Massager (model: FE-7204B) is a powered inflatable tube massager intended to be an over-the counter portable inflatable tube massage system which simulates kneading and stroking of foot, calf, and thigh by the use of inflatable air compression boots. The device can be used to temporarily increase blood circulation and temporarily relieve minor muscle aches and pains. The device is to be used by persons who are in good health.

The device is non-sterile and utilizes the pneumatically controlled chambers actuated by an electronically controlled air pump and two solenoid valves. The pump, solenoids and other components are protectively housed within the acrylonitrile butadiene styrene (ABS) plastic enclosure of the control unit. On the bottom of the control unit, there are 3 ports which include the following:

- Two ports (L and R) for connecting the air compression boots (left (L) and right (R)) by the air hose which is permanently attached to the air compression boots
- One port for connecting the alternating current (AC) adaptor which will convert line power into direct current (DC) power.

The subject device is comprised of the following components:

- Control Unit
- AC Adapter (input:100-240V AC 50/60Hz 0.7A, output 12.0VDC, 2.0A) for converting line power to DC power
- Connector Air Hose (connects Control Unit to the inflatable air compression boots)
- Air compression boots which consist of three (3) air chambers/bladders encased inside a soft medical material.

Characteristics of Air Compression Leg Massager (Model: FE-7204B)

No	Characteristics
1	Powered by AC Adapter (input:100-240V AC 50/60Hz 0.7A, output 12.0VDC, 2.0A)
2	Power consumption: 24 W
3	Size of the control unit (±0.5cm) (Length 20cm ×Height 5.0cm× Width5.5cm)
4	Massage intensity (weak-medium-strong) Foot: Weak: 23±2kPa Medium: 27±2kPa Strong: 31 ±2kPa Calf: Weak: 23±2kPa Medium: 27±2kPa Strong: 31 ±2kPa Thigh: Weak: 23±2kPa Medium: 27±2kPa Strong: 31 ±2kPa
5	LCD backlight
6	LCD size (viewing area ±0.2cm)(2.0cm×3.5cm)
7	Size of Inflatable boots(Size: ±2cm) 1) Size: 71.5cm ×25cm 2） The boots are suitable for the users with the following: ● Foot width : about 12 cm to about 16 cm. ● Calf diameter: about 16.5 cm to about 24cm. ● Thigh diameter: about 19 cm to about 33cm.
8	Picture of the boots  **A pair of boots are exclusively for single person use only.**
9	Boots material: Nylon with a polyurethane laminate, and Velcro made of nylon Air bladder/chamber: TPU (Thermoplastic polyurethanes) Plastic components: 1. Control unit enclosure: acrylonitrile butadiene styrene (ABS)

	2. Lens: PMMA (polymethyl methacrylate) 3. Air hose: PVC (polyvinyl chloride)

Intended Use/Indication for use :

Air compression leg massager, model:FE-7204B, is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated foot/calf and thigh in people who are in good health. The air compression leg massager simulates kneading and stroking of tissues by using air-inflatable boots.

Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following standards in connection with medical device electrical safety, electromagnetic compatibility, biocompatibility, and software verification and validation:

(a) ANSI/AAMI ES60601-1 Medical Electrical Equipment-Part1: General Requirements for safety, 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012.

(b) 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, 2014.

(c) IEC 60601-1-11, Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance-Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, Edition 2.0 2015-01.

(d) ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.

(e) ISO 10993-10:2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

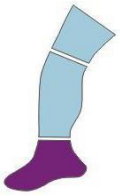
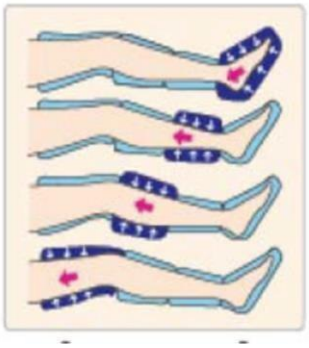
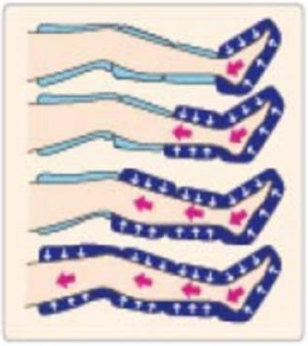
(f) Guidance for the content of Premarket Submissions for Software Contained in Medical Devices.

Technological comparison with the predicate device:

Compared with the predicate device, the subject device is similar in design principle, intended use, indications for use, functions, and material, and have been tested to applicable standards. The differences between subject device and predicate device do not raise new questions of safety or effectiveness. See comparison below:

Elements of comparison	Subject device K211850 ）	Predicate Device (K182668)	Conclusion
Manufacturer	Xiamen Healthpal Electronic Co., Ltd.	Rapid Reboot Recovery Products, LLC	--
Product model	FE-7204B	Rapid Reboot Compression Therapy System	--
Regulation name	Powered Inflatable Tube Massager	Powered Inflatable Tube Massager	Identical

Regulation class	II	II	Identical
Regulation number	21 CFR 890.5650	21 CFR 890.5650	Identical
OTC or Rx	OTC	OTC	Identical
Indications for use	Air compression leg massager, model:FE-7204B, is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated foot/calf and thigh in people who are in good health. The air compression leg massager simulates kneading and stroking of tissues by using air-inflatable boots.	The Rapid Reboot Compression Therapy System is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	Similar Note 1
Intended use environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Treatment area	Leg (including Foot, calf and thigh)	Leg (including Foot, calf and thigh), Hip, arm	Similar Note 2
Therapy time	20 minutes	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	Different Note 3
	The subject device consists of an air pump, two solenoid valves, and air compression boots working together as one unit. By inflating and deflating the air chambers through the control of	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), one at a time. "B" mode also inflates chambers from bottom up, but	

Modes (visual description)	working and/or not working air pump and solenoid valves at a regular pace and different timing, the components simulate kneading and stroking of the foot, calf and thigh. There are 3 modes for the subject device. **Mode 1: Pressing**  Massage the foot, calf and thigh, **Mode 2: kneading**  Massage the calf-thigh **Mode 3: Shiatsu**  Massage the foot	maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated. Mode A:  Mode B: 	Different Note 4
Output pressure range	0-33 kPa	0-200 mmHg	Different Note 5
Power source	AC100-240V,50/60Hz	110 V, 60Hz	Different Note 6
Power consumption	24W	30W	Different Note 7
Photo/size of the control unit	 (Length 20cm ×Height 5.0cm× Width5.5cm)	 10” x 6.5” x 5”（in）	Different Note 8
Weight	About 1.25kg	5.8 pounds	Different Note 9

Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Identical
Photo and size of the boots for leg (foot, calf and thigh)	 Size: 71.5cm ×25cm **The feet, calves and thighs which are suitable for the users with the following measurements:** ● Foot width : about 12 cm to about 16 cm. ● Calf diameter: about 16.5 cm to about 24 cm. ● Thigh diameter: about 19 cm to about 33 cm **A pair of boots is for single person use only.**	 X-Short: 14” x 41” Short: 14” x 43” Medium: 14” x 45” Long: 14” x 48” X-Long: 14” x 52”	Different Note 10
Safety Features	Button on display allows user to stop or pause therapy session at any time.	Button on display allows user to stop or pause therapy session at any time.	Identical
Number of chambers	3-chamber	4-chamber	Different Note 11
Sleeve materials	Nylon with a Polyurethane laminate	Nylon with a Polyurethane laminate	Identical
Mode of compression	Sequential	Sequential	Identical
Patient contact	Non-conductive appliances	Non-conductive appliances	Identical
Software/ firmware/ microprocess or control	Microprocessor	Microprocessor	Identical
FDA-recognized standards			
Electrical safety, EMC, Bio-compatibility	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC60601-1-11 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC60601-1-2 ISO 10993-5 ISO 10993-10	Similar Note 12

Note 1 and Note 2:

The predicate device covers the leg (consisting of foot, calf, knee, upper leg), hip and arm. The subject device covers similar treatment areas including the foot, calf and thigh.

Note 3 and Note 4:

Although the subject device is different than the predicate device in therapy time and massage mode, the subject device has been tested per ANSI/AAMI ES60601-1，IEC 60601-1-2, IEC 60601-1-11, and the software of the subject device has been validated

per the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, so the difference of therapy and massage modes would not adversely impact safety and effectiveness.

Note 5, Note 6 and Note 7:

Although the subject device is different than the predicate device in output pressure range and power source and power consumption, the subject device has been tested per ANSI/AAMI ES60601-1，IEC 60601-1-2 and IEC 60601-1-11, so the difference would not adversely impact safety and effectiveness.

Note 8 and Note 9:

Although the subject device is different than the predicate device in the weight and the size of control unit, it is believed that the difference in design would not adversely impact safety and effectiveness.

Note 10:

Although the subject device is different than the predicate device in boot size, it is believed that the difference in design would not adversely impact safety and effectiveness.

Note 11:

Although the subject device is different than the predicate device as it pertains to the air chamber, the subject device has been tested per ANSI/AAMI ES60601-1，IEC 60601-1-2 and IEC 60601-1-11, so the difference would not adversely impact safety and effectiveness.

Note 12：

The subject device was tested per the standards noted for the predicate device (ANSI/AAMI ES60601-1, IEC 60601-1-2, ISO 10993-5, and ISO 10993-10), in addition to IEC 60601-1-11.

Summary for clinical test:

Clinical performance is not deemed necessary.

Conclusions:

The Air compression leg massager（model:FE-7204B) has the same indication for use and similar technological characteristics when compared to the predicate device, the Rapid Reboot Compression Therapy System (K182668).Moreover, verification and validation tests contained in this submission demonstrate that the differences between the subject and the predicate devices does not:

(1) affect the intended use or (2) alter the safety of the device, and the subject device a is considered substantial equivalent to the predicate device.