March 15, 2023

Xiamen Emoka Health Science & Technology Co., Ltd.
Iris Fung
Regulation Manager
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong 361000
China

Re: K222991
Trade/Device Name: Air Compression Leg Massager (model: EMK-701)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 28, 2022
Received: September 28, 2022

Dear Iris Fung:

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director
THT5B3: 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)*
K222991

Device Name
Air Compression Leg Massager (model: EMK-701)

Indications for Use *(Describe)*
Air Compression Leg Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. Air Compression Leg Massager simulates kneading and stroking of tissues by using an inflatable garment.

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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Date of the summary prepared: Mar10, 2023

510(k) Summary

510K: K222991

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a ***Traditional 510(K)*** submission, and there were no prior submissions for the subject device.

1. Submitter's Information

Sponsor

- Company Name: Xiamen Emoka Health Science & Technology Co., Ltd.
- Address: D Building, No.100, Jinfu Road, Chengnan Industrial Zone, Tong'an District, Xiamen, China
- Phone: +86-592-7363861
- Email: emk@emoka.cn
- Contact Person (including title): Zhang Feng (Quality Manager)

Application Correspondent:

- Xiamen Emoka Health Science & Technology Co., Ltd..
- Address: D Building, No.100, Jinfu Road, Chengnan Industrial Zone, Tong'an District, Xiamen, China
- Contact Person: Ms. Iris Fung
- Title: Regulation Manager
- Tel: +86-18588874857
- Email: mdc-fs@foxmail.com; jianda-lee@foxmail.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Classification: Powered Inflatable Tube Massager
- Trade Name: Air Compression Leg Massager
- Model: EMK-701
- Review Panel: Physical Medicine
- Product Code: IRP
- Regulation Number: 21 CFR 890.5650
- Regulation Class: 2

3. Predicate Device Information

Predicate Device I

- 510(k) number: K193354

- Sponsor: Shenzhen Dongjilian Electronics Co., Ltd.
- Classification: Powered Inflatable Tube Massager
- Trade Name: Air Compression Therapy Device
  Model: S9019
- Review Panel: Physical Medicine
- Product Code: IRP
- Regulation Number: 21 CFR 890.5650
- Regulation Class: 2

Predicate Device II

- 510(k) number: K212935
- Sponsor: Xiamen Simo Electronic Co., Ltd
- Classification: Powered Inflatable Tube Massager
- Trade Name: Air Pressure Foot Massager
- Model: SM-512F
- Review Panel: Physical Medicine
- Product Code: IRP
- Regulation Number: 21 CFR 890.5650
- Regulation Class: 2

4. Device Description

Air Compression Leg Massager (Model: EMK-701) is a portable and rechargeable device. It is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue with the hands by use of inflatable pressure cuffs. It can be used to temporarily increase blood circulation and temporarily relieve minor muscle aches and pains.

Air Compression Leg Massager supplied clean and non-sterile, utilizes the pneumatically controlled leg wraps actuated by an electronically controlled air pump unit. A pump, battery and control components are protectively housed in a plastic case of Handheld Controller. Function buttons and light emitting diode (LED) indicators on the Handheld Controller make up the user interface. There are 3 ports at the bottom of Handheld Controller for connecting the alternating current (AC) adapter plug and two air hoses.

Each leg wrap has an air hose for connection to Handheld Controller, and both encase a 2-chamber air bladder inside. Feet and calves can be wrapped and massaged separately by the two chambers. The soft medical fabric of wraps provides patient comfort and biocompatibility compliance.

In operation, the user turns the power on via the Power button. Then the Handheld Controller controls the inflating and deflating of the air bladders according to preset program

parameters. The air pressure is monitored by an internal pressure sensor and microprocessor. Once the pressure of the air bladder reaches the proper level, the pump is turned off for a rest period. The cycle of inflation and deflation repeats until the unit is turned off.

5. Intended Use / Indications for Use

Air Compression Leg Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. Air Compression Leg Massager simulates kneading and stroking of tissues by using an inflatable garment.

6. Test Summary

Air Compression Leg Massager has been evaluated for its safety and performance by lab bench testing as following:

- ANSI/AAMI ES60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
- IEC 60601-1-11:2015 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
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

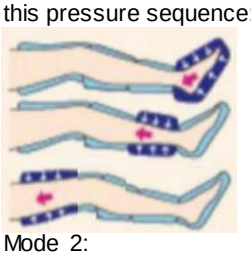
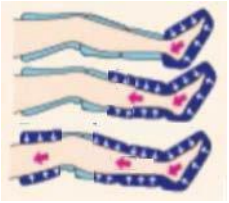
7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Air Compression Leg Massager is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of comparison	Subject Device	Predicate Device I	Predicate Device II	Comparison
Manufacturer	Xiamen Emoka Health Science & Technology Co., Ltd.	Shenzhen Dongjilian Electronics Co., Ltd.	Xiamen Simo Electronic Co., Ltd	--
510K number	K222991	K193354	K212935	--

Elements of comparison	Subject Device	Predicate Device I	Predicate Device II	Comparison
Product Name	Air Compression Leg Massager EMK-701	Air Compression Therapy Device S9019	Air Pressure Foot Massager SM-512F	--
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	Powered inflatable tube massager	--
Regulation Class	2	2	2	--
Product code	IRP	IRP	IRP	--
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	--
OTC & Rx	OTC	OTC	OTC	Same
Indications for Use	Air Compression Leg Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. Air Compression Leg Massager simulates kneading and stroking of tissues by using an inflatable garment.	The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.	Air Pressure Foot Massager is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	Minor difference Note 1
Power Source	Input: AC100-240V, 50/60Hz Output: DC 13.5V, 1A Internal battery: 11.1V, 1000mAh	100~240V 50/60Hz	Voltage: DC5V 1A Lithium Battery: 3.7V, 2400mah	Minor difference Note 2
Power consumption	13.5 W	12W	5W	Minor difference Note 2
Dimensions (W*H*D)	215*50*70 mm	10.2*5.9 *25.6 inch	211*55*50mm	Minor difference Note 2
Photo			Not publicly available	Minor difference Note 2
Weight	2.0 Kg (4.4pounds)	4.6 pounds	1.15±0.1kg	Minor difference Note 2
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Not publicly available	Same
Sleeves Dimensions	Leg Wrap: 730*468 mm	Leg Wrap: 730*260 mm	340*365*360mm	Minor difference

Elements of comparison	Subject Device	Predicate Device I	Predicate Device II	Comparison
				Note 3
Application area	Leg (feet, calves)	Leg (feet, calve, thigh)	Feet	Minor difference Note 3
Number of Chambers	2-chamber	3-chamber	2-chamber	Minor difference Note 3
Sleeve Materials	Dacron	Nylon with a Polyurethane laminate	Terylene	Minor difference Note 3
Mode of Compression	Sequential	Sequential / Peristaltic	Sequential	Same
Air Pressure Level	Low level: 120mmHg Medium level: 170mmHg High level: 210mmHg Error range: ±25mmHg	Low level: 150mmHg; Mid level: 185mmHg; High Level: 215mmHg Error range: ±25mmHg	30-110mmHg	Minor difference Note 4
Treatment Time	15 minutes	20 minutes	0-30min, default as 15min	Minor difference Note 5
Inflation time	5 – 18 s	3 – 30 s	Not publicly available	Minor difference Note 6
Keep time	2 - 5 s	1 - 5s	Not publicly available	
Deflation time	2 – 5 s	1 - 5s	Not publicly available	
Cycle time	Range of 26 sec to 1 min 29 sec	Range of 25 sec to 3 min 40 sec	Not publicly available	
Work Mode	Mode 1: The model is divided into three processes. The first process is starting with foot chamber inflates and holds the air until the calf chamber is compressed. Then deflates simultaneously. The second process is starting with foot chamber inflates and holds the air until the calf chamber	Mode 1: Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the thigh section decompresses, the cycle	Mode 1 The model is divided into two processes, the first process includes inflating, deflating and holding pressure. The inflating sequence of air chambers of sleeves is: The chamber No.① Inflate and keep pressure three times, deflated, Then the chamber	Minor difference Note 6

Elements of comparison	Subject Device	Predicate Device I	Predicate Device II	Comparison
	is compressed. Then calf chamber deflates, and finally foot chamber deflates. The third process is starting with calf chamber inflates and deflates then. Mode 1 follows this pressure sequence: Foot → Foot + Calf → Interval → Foot → Foot + Calf → Foot → Interval → Calf Mode 2: In this model, foot chamber and calf chamber are inflated and deflated at the same time. Mode 2 follows this pressure sequence: Foot + Calf → Interval → Foot + Calf The inflating and deflating time are different according to the intensity selected.	begins again. Mode 1 follows this pressure sequence:  Mode 2: Starting with the foot chamber and progressing up the thigh, each section compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All three sections then decompress simultaneously and the air pressure drops, then cycle begins again. Mode 2 follows this pressure sequence:  Mode 3: include two stage, stage 1: it works according to the method of mode 1, after the stage 1 is completed, it goes to stage 2(working according to the method of mode 2) without interruption time until finish the stage 2, then enter next cycle without interruption. The pressure sequence of mode 3 combines mode 1 and mode 2	No ② inflate and keep pressure three times, deflated. In the second process, the air pump is always opened, and the air is inflated and deflated according to the following inflating sequence: ①②—①—②-①②—①—②—①—②—①②—①-②—①②—①—② —①— ②—① The inflating time is different according to the intensity selected. Mode 2 In this model, at first, the chamber No. ① inflate and keep pressure four times, then chamber No. ①② are inflated and deflated at the same time. Mode 3 The chamber No. ①② are inflated and deflated at the same time, Then the cycle repeats	
Noise level	≤ 65 dB	≤ 65 dB	Not publicly available	Same
Patient contact	Non-conductive appliances	Non-conductive appliances	Not publicly available	Same

Elements of comparison	Subject Device	Predicate Device I	Predicate Device II	Verdict
Software/Firmware Microprocessor Control	Microprocessor	Microprocessor	Not publicly available	Same
Technology	Compressor and valve system which sequentially inflates cells of appliance	Not publicly available	Compressor and valve system which sequentially inflates cells of appliance	Same
Safety Features	Power button allows user to stop therapy session at any time	Standby button allows user to stop therapy session at any time	Not publicly available	Same
Operating environment	Temperature: 5℃-40℃ Humidity: 5%- 90% non-condensing	Temperature: 5℃-40℃ Humidity: 5%- 90% non-condensing	Not publicly available	Same
Transportation & Storage environment	Temperature: -20℃~55℃ Humidity: 5%-90% noncondensing Atmospheric Pressure: 75-106kPa	Temperature: 20℃~55℃ Humidity: 5%-90% noncondensing Atmospheric Pressure: 75-106kPa	Not publicly available	Minor difference Note 2
Electrical safety, EMC	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 61233	ES 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 61233	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

Note 1

Although there are minor differences in the indications for use when compared to the predicate devices, the intended use is the same. This difference does not affect the safety and effectiveness.

Note 2

Although the subject device design and specification parameter between the predicate devices and subject device are different, all complied with the 60601-1 standard. So the differences on such parameters (power, dimensions, appearance,) do not affect the safety and effectiveness.

Note 3

Although the subject device provides 2-chamber wraps for the feet and calves area, which are differents in size and appearance when compared to the predicate devices, the chamber number and applicable body areas are included in the predicate devices, and the material also complies with the applicable ISO 10993-5 and ISO 10993-10 standards. Therefore, the difference does not impact safety and effectiveness.

Note 4

Although the pressure range of subject device is different than the predicate devices, the range is contained within the predicate devices, so the difference would not impact safety and effectiveness.

Note 5

The treatment time of subject device is 15 minutes, this is similar to both predicate devices and within the range outlined for predicate device II. The user can choose the frequency of treatment and discontinue treatment, so the difference of treatment time would not impact safety and effectiveness.

Note 6

Although the subject device provides 2 work modes, which are not completely the same as the predicate devices, the modes of subject device only have differences in the inflatable order of the different chambers. The treatment pressure range are the same under the different modes, so the different modes would not impact safety and effectiveness.

8. Summary for clinical test

No Clinical Test conducted.

9. Conclusion

The subject device Air Compression Leg Massager has the same intended use as the predicate devices. The few differences outlined do not affect the safety and effectiveness of the subject device when compared to the noted predicate devices. Thus, the subject device is substantially equivalent to the predicate devices.