March 14, 2023

Zhangzhou Easepal Innovation Co Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
GuangZhou City, China
Guangzhou, Guangdong 510000
China

Re: K223464
Trade/Device Name: Leg and Foot Air Wave Pressure Therapy Device
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: March 3, 2023
Received: March 3, 2023

Dear Jet Li:

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,

Heather L. Dean -S

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)*
K223464

Device Name
Leg and Foot Air Wave Pressure Therapy Device

Indications for Use *(Describe)*
Leg and Foot Air Wave Pressure Therapy Device EP-1129 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, it can simulate 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.

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.

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510(k) Summary

K223464.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements according to 21 CFR 807.92 (c), and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: ZHANGZHOU EASEPAL INNOVATION CO., LTD.

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Application Correspondent: Jet Li

Company: Guangzhou KEDA Biological Technology Co., Ltd

E-mail: med-jl@foxmail.com

Phone: 86-18588874857

Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: **Leg and Foot Air Wave Pressure Therapy Device**

Model: EP-1129

Classification Name: Powered inflatable tube massager

Review Panel: Physical Medicine

Product Code: IRP

Regulation Number: 21 CFR 890.5650

Regulation Class: 2

3. Predicate and Reference Device Information

Item	Predicate Device	Reference Device
Sponsor	Shenzhen Dongjilian Electronics Co., Ltd.	Ceragem International, Inc.
Device Name	Air Compression Therapy Device	Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702
510(k) Number	K193354	K220572
Product Code	IRP	IRP
Regulation Number	21 CFR 890.5650	21 CFR 890.5880, 21 CFR 890.5650
Regulation Class	2	2

4. Device Description

Leg and Foot Air Wave Pressure Therapy Device EP-1129 is a powered inflatable tube massager, comprised of an air compressor with intermittent pneumatic controller, 3-chamber sleeves covered with polyester fiber, and a connectable hose for connecting the device to the sleeves.

The device can be powered by an external power supply, or be powered by an internal lithium ion battery. The sleeves have 3-chambers and different applicable body areas, such as the Foot/ Leg. The sleeves can be inflating and deflating sequentially to apply the circulating pressure on the target body areas which controlled by the main unit.

The device simulates manual kneading and stroking of tissues by sequential inflated sleeves, to temporarily relieve minor muscle aches and/or pains and to temporarily increase circulation to the treated areas. It is to be used by adults who are in good health.

The recommended treatment time is 15 minutes per time, and recommend to take one time treatment every two days.

5. Intended Use/Indication for use

Leg and Foot Air Wave Pressure Therapy Device EP-1129 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, it can simulate kneading and stroking of tissues by using an inflatable garment.

6. Test Summary

Non Clinical testing:

The Leg and Foot Air Wave Pressure Therapy Device has been evaluated the safety and performance by lab bench testing according to the following standards:

- ANSI/AAMI ES60601-1: 2005+A1:2012; AMD2:2021, Medical Electrical Equipment - Part 1: General Requirements for Safety,
- IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests

- IEC 60601-1-11 Edition 2.0 2015-01, 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,
- 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
- The software was validated according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The device also was verified with the following benching testing and usability study:

- Product service life verification
- Burst Strength Test
- Product performance testing after reliability testing

Tests results are supporting all labeling claims in order to establish substantial equivalency.

Usability Study was completed in the subject device:

A human Factors Validation Testing was done to evaluate the HFE/ UE concerns, including label comprehension/self-selection and usability/user interface studies.

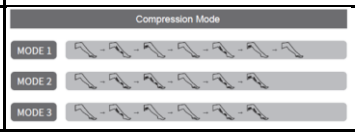
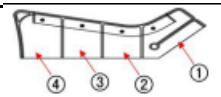
Clinical testing: Clinical testing is not necessary for the subject device.

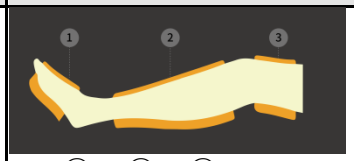
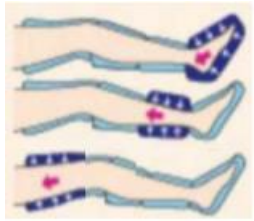
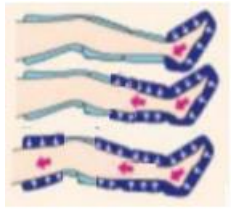
7. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.
See the below form.

Elements of comparison	Subject Device	Predicate Device	Reference Device
Manufacturer	ZHANGZHOU EASEPAL INNOVATION CO., LTD.	Shenzhen Dongjilian Electronics Co., Ltd.	Ceragem International, Inc.
510K number	K223464	K193354	K220572
Product Name	**Leg and Foot Air Wave Pressure Therapy Device** Model EP-1129	Air Compression Therapy Device (S9019)	Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5880, 21 CFR 890.5650
Classification Name	Powered inflatable tube massager	Powered inflatfable tube massager	Powered inflatfable tube massager
Regulation Class	2	2	2
OTC & Rx	OTC	OTC	OTC
Indications for Use	**Leg and Foot Air Wave Pressure Therapy Device** EP-1129 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, it can simulate 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.	The intended use of the Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702 is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for: -Temporary relief of minor muscle and joint pain stiffness -Temporary relief of minor joint pain associated with arthritis -Temporary increase in local circulation where applied - Relaxation of muscles The Air Cell Massager (only CGM MB-1701) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in

Elements of comparison	Subject Device	Predicate Device	Reference Device
			blood circulation to the treated areas. The Air Cell Massager stimulates kneading and stroking of tissues by using an inflatable garment.
Power Source	AC100-240V, 50/60Hz	100~240V 50/60Hz	100-127Vac 50/60Hz
Power consumption	11.1W	12W	480VA
Dimensions (W*H*D)	340*210*850mm	10.2*5.9*25.6 (in)	/
Photo			/
Weight	2.0 Kg(4.4pounds)	4.6 pounds	/
Size and appearance of sleeves (leg part)	 One size: 85*34 cm	 One size: 73*26 cm	Leg:  One size: 28*58.4cm
Inflation time	20-50 s	3-30 s	1 min ~ 1 min 30 s
Keep time	1-3 s	1-5 s	1 ~ 13 s

Elements of comparison	Subject Device	Predicate Device	Reference Device
Deflation time	5 s	1-5 s	1 ~ 10 s
Cycle time	30 seconds to 3 mins	Range of 25 sec to 3 min 40 sec	Range of 28 sec to 39 sec
Number of Chambers	3 Chambers	3 Chambers	4 Chambers
Sleeve Materials	Tribute satin and Oxford cloth	Nylon with a Polyurethane laminate	Oxford and Nylon
Mode of Compression	Sequential	Sequential	Sequential
Device Pressure range	90-225mmHg	0-240 mmHg	48~240 mmHg
Air pressure level /Compression levels	4 levels settings: Level 1:90mmHg; Level 2:135mmHg; Level 3: 188mmHg Level 4: 225mmHg	3 levels settings: low level:150mmHg; Mid level:185mmHg; High Level: 215mmHg	9 levels settings: Level 1 : 48mmHg Level 2 : 72mmHg Level 3 : 96mmHg Level 4 : 120mmHg Level 5 : 144mmHg Level 6 : 168mmHg Level 7 : 192mmHg Level 8 : 216mmHg Level 9 : 240mmHg
Treatment Time	Default as 15min	20 min	18 minutes
Work Mode		**Mode 1:** Starting with the foot chamber and progressing up the thigh chamber, each	

Elements of comparison	Subject Device	Predicate Device	Reference Device
	 M1: ① ➞② ➞③ (sole air bags inflate - deflate - calf air bag inflates – deflate - thigh air bags inflate - deflate – cycle in turn) M2: ① ➞ ①②➞ ①②③ (Sole air bags inflate - pressure maintaining-- calf air bag inflate --pressure maintaining- thigh air bags inflate - sole, calf, thigh air bags deflate simultaneously -- cycle in turn) M3: ① ➞② ➞③ ➞ ① ➞ ①② ➞ ①②③ (Sole air bags inflate - deflate - calf air bag inflates – deflate - thigh air bags inflate - deflate - sole air bags inflate - pressure maintaining - calf air bag inflates – pressure maintaining - thigh air bags inflate- sole, calf, thigh air bags deflate simultaneously– cycle in turn) Cycle in turn.	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 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 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 begins again. 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 four sections then decompress simultaneously, and the air pressure drops, then cycle begins again. Mode 3: Start between the foot chamber to the thigh chamber except for No. 4 chamber. And No.4 chamber is compressed while the other chambers are maintained. After that all four sections decompress simultaneously and the air pressure drops, then cycle begins again. This sequence is similar to the Mode 2.

Elements of comparison	Subject Device	Predicate Device	Reference Device
		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. Mode1 ⇄ Mode2 The pressure sequence of mode 3 combines mode 1 and mode 2	
Patient contact	Non-conductive appliances	Non-conductive appliances	Non-conductive attachments
Software/Firmware/Microprocessor Control	Microprocessor	Microprocessor	Microprocessor
Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance
Electrical safety, EMC	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62133	ES 60601-1; IEC 60601-1-2; ISO 10993-5; ISO 10993-10; IEC 60601-1-11	ANSI AAMI ES60601-1:2005 IEC 60601-1-2 Edition 4.0 IEC 60601-1-6 Edition 3.1 IEC 60601-1-11 Edition 2.0 ISO 10993-5 Third edition ISO 10993-10 Third Edition

8. Conclusion

The subject device **Leg and Foot Air Wave Pressure Therapy Device** has all features of the predicate devices for intended use. Thus, the subject device is substantially equivalent to the predicate devices.

9. Summary Prepared Date

3 March 2023