March 17, 2025

Jiale Health Technology Shenzhen Co., Ltd.
℅ Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K242140
Trade/Device Name: Air Compression Leg Massager (K-705)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IRO
Dated: January 15, 2025
Received: February 26, 2025

Dear Youshan Gong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K242140

Please provide the device trade name(s).

Air Compression Leg Massager (K-705)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K242140

"510(k) Summary" as required by 21 CFR Part 807.92.

Date Prepared: 2025-3-11

I. Submitter

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II. Device

Name of Device: Air Compression Leg Massager
Model(s): K-705
Common or Usual Name: Massager, Powered Inflatable Tube
Regulation Name: Powered inflatable tube massager
Regulatory Class: II
Product Code: IRP, IRO
Regulation Number: 21 CFR 890.5650, 21 CFR 890.5975

III. Predicate Device and Reference Device

- **Predicate Device**

Manufacturer	Predicate Device	510(k) Number
Xiamen Emoka HealthScience& Technology Co., Ltd.	Air Compression Leg Massager (model: EMK-701)	K222991

- **Secondary Predicate Device**

Manufacturer	Reference Device	510(k) Number
THERABODY, Inc	JetBoots PRO Plus	K241256

IV. Device Description

Air Compression Leg Massager 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 Controller.

Function buttons and light emitting diode (LED) indicators on the Controller make up the user interface. There is a charging port at the bottom of Controller for connecting the alternating current (AC) adapter plug.

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

Air Compression Leg Massager is also capable of providing the warming and vibration, these are included for an improved user experience.

V. 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.

VI. Materials

Model	Contacted Component Name	Materials
K-705	Leg wraps	Nylon polyester
	Enclosure of Controller	ABS, PC

VII. Comparison of Technological Characteristics With the Predicate Device

The Air Compression Leg Massager (K-705) has the same intended use as the predicate devices . The technological characteristics such as application area, number of chambers, air pressure level and treatment time, are similar to the primary predicate device and secondary predicate device. Any minor differences between the subject device and the listed primary predicate device and secondary predicate device do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the primary predicate device and secondary predicate device for its intended use.

Therefore, the Air Compression Leg Massager may be found substantially equivalent to its primary predicate device and secondary predicate device.

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
510(k) Number	K242140	K222991	K241256	/

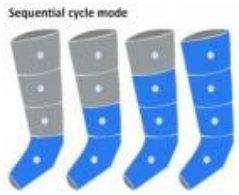
Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Trade name	Air Compression Leg Massager	Air Compression Leg Massager (model: EMK-701)	JetBoots PRO Plus	/
Manufacturer	Jiale Health Technology Shenzhen Co., Ltd.	Xiamen Emoka HealthScience& Technology Co., Ltd.	THERABODY, Inc	/
Regulation number	21 CFR 890.5650 21 CFR 890.5975	21 CFR 890.5650	21 CFR 890.5650 21 CFR 890.5500 21 CFR 890.5975	Same
Device class	II	II	II	Same
Product code	IRP, IRO	IRP	IRP, ILY, IRO	Same

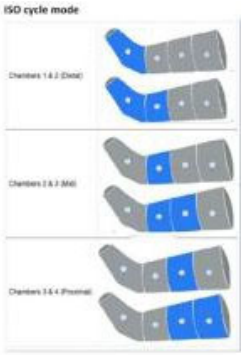
Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Indication for use	Air Compression Leg Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary 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.	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.	JetBoots PRO Plus is an air compression therapy device intended to provide graduated pressure to the legs. JetBoots PRO Plus is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the treated area in people who are in good health. JetBoots PRO Plus simulates kneading and stroking of tissues by using an inflatable garment.	Same
Prescription or OTC	Over-The-Counter Use	Over-The-Counter Use	Over-The-Counter Use	Same
Power Source	Input: AC100-240V,50/60HZ Output: DC5V/1A Internal battery: 3.7V 2500mAh	Input: AC100-240V, 50/60Hz Output: DC 13.5V, 1A Internal battery: 11.1V,1000mAh	Power Adapter: AC Input: 100 –240V AC, 50/60Hz, DC Output: 15.0V, 4.8A, 72W Or Internal Battery	Different

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Power consumption	6.5W	13.5 W	72W Or Internal Battery	Different
Dimensions (W*H*D)	358*172*67mm	215*50*70 mm	Console & Compression boot (Lead or Support, deflated and fully extended): • S-size: 36.8in (L) * 5.3in (W) * 14.8 (H) • M-size: 42.9in (L) * 5.3in (W) * 16.1 (H) • L-size: 46.5in (L) * 5.3in (W) * 16.1 (H)	Different
Weight	0.59kg(1.28pounds)	2.0 Kg (4.4pounds)	S-size: 6.0lb (per boot) M-size: 6.4lb (per boot) L-size: 6.7lb (per boot)	Different
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Molded PC+ABS enclosure	Same

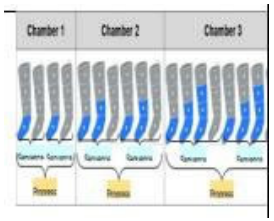
Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Sleeves Dimensions	Leg Wrap: 350*628mm	Leg Wrap: 730*468 mm	Compression boots sleeves attached to consoles. Sleeves (extended) only: S: 80cm (L)* 37.5 cm (H) M: 95cm (L)* 41.0 cm (H) L: 1050cm (L)* 41.0 cm (H)	Different
Application area	Leg (calves)	Leg (feet, calves)	Leg (feet, calve)	Different
Number of Chambers	2-chamber	2-chamber	4-chamber	Different
Sleeve Materials	Nylon polyester	Dacron	Polyether Nylon Fabric	Different
Mode of Compression	Sequential	Sequential	No related information	Same

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Air Pressure Level	Low level: 120mmHg Medium level: 170mmHg High level: 210mmHg Error range: ±25mmHg	Low level: 120mmHg Medium level: 170mmHg High level: 210mmHg Error range: ±25mmHg	20 – 100 mmHg, steps of 5mm Hg	Same
Treatment Time	15 minutes	15 minutes	10min – 60min, steps of 5min for Pneumatic Compression 10min – 45min for Infrared LED	Same
Inflation time	2-12s	5 -18 s	No related information	Different
Keep time	3-6s	2 - 5 s	0 – 10 seconds depending on the selected preset.	
Deflation time	1-6s	2 - 5 s	No related information	

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Cycle time	Range of 6sec to 1 min 2.0sec	Range of 26 sec to 1 min 29 sec	Pause interval between cycles: 15 seconds	
Work Mode	The model is divided into three processes. Mode 1：The upper leg air bag is pressurized, then the lower air bag is pressurized, and then the pressure is relieved, and then the above process is repeated. Then the upper and lower is pressurized at the same time, and then the static pressure is maintained. And then the cycle is repeated. The air pressure of Mode 1 is 120mmHg.	Mode 1: The model is divided into three processes. The first process is starting w ith 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 is compressed. Then calf chamber deflates, and finally foot chamber deflates. The third process is starting with calf chamber inflates and deflates then.	Sequential, ISO, or Static Flow Cycles Sequential mode that applies a directional massage, starting at the base of the treated area, and progresses upwards towards the torso and then releases.  ISO mode that applies a directional	Different

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
	 Mode 2: The lower air bag is pressurized→ pressure retention → pressure→ pressure retention →pressure relief. And then the cycle is repeated. The air pressure of Mode 2 is 170mmHg.  Mode 3: The upper and lower pressure is pressurized at the same time →The upper pressure → pressure relief. And then the cycle is repeated.	Mode 1 follow s 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 follow s this pressure sequence: Foot + Calf → Interval → Foot+ Calf The inflating and deflating time are different according to the intensity selected.	massage to a smaller, user- selected area. The first chamber inflates, and after a few seconds, the second chamber starts to inflate until both chambers reach the set pressure. Then both chambers deflate, and after a pause the process starts again.  Flow cycles Progress 1: first inflate Chamber 1 to target pressure, then hold & release. then go to Progress 2.	

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
	The air pressure of Mode 3 is 210mmHg. 		Progress 2: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2 for specified time, then release totally, then go to Progress 3 Progress 3: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1, 2, 3 for specified time then release totally. then go to Progress 4.Progress 4: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. when Chamber 2 reach the target pressure, hold chamber 1 & 2, & start to inflate	

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
			Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1, 2, 3,& start to inflate Chamber 4, when Chamber 4 reach to the target pressure, then hold chamber 1, 2, 3 &4 for specified time then release totally. then go back to Progress 1 again.  Static Cycle The chambers inflate one at the time starting at chamber 1 while maintaining negative gradient of compression along the leg. The pressure is limited to 20 mmHg to 30 mmHg. Once inflated, the chambers do not deflate during	

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
			the treatment. While the garment is inflated, it comes in contact with the legs to optimize the treatment of vibration and infrared LED light by ensuring optimal contact with the leg.	
Noise level	≤ 65 dB	≤ 65 dB	No related information	Same
Patient contact	Non-conductive appliances	Non-conductive appliances	Non-conductive appliances	Same
Softw are/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Microprocessor	Same
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, Light Emitting Diodes	Same
Safety Features	Power button allows user to stop therapy session at any time	Power button allows user to stop therapy session at any time	No related information	Same

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
Operating environment	Temperature: 5℃-35℃ Humidity: 5%- 90% non-condensing Atmospheric Pressure: 75-106kPa	Temperature: 5℃-40℃ Humidity: 5%- 90% non condensing	No related information	Same
Transportation & Storage environment	Temperature: -20℃~55℃ Humidity: 5%-90% non condensing Atmospheric Pressure: 75-106kPa	Temperature: -20℃~55℃ Humidity: 5%-90% non condensing Atmospheric Pressure: 75-106kPa	No related information	Same
Level of heating	Low temperature: 35℃ Medium temperature: 38℃ High temperature: 41℃ Error range: ±2℃	N/A	Maximum Device Surface Temperature: 43.2° C Highest Measured Skin Temperature During Treatment: 36.8° C	Different
Level of vibration frequency	Constant frequency 150Hz(±15Hz) Low level: 1 second on, 3 seconds off Mid level: 1 second on, 2	N/A	No related information	Different

Comparison Elements	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Model	**K-705**	**EMK-701**	**JetBoots PRO Plus**	**/**
	seconds off High level: 0.5 second on, 0.5 seconds off			
Electrical safety, EMC	IEC 60601-1 IEC 60601-1-2 IEC 62133-2 IEC 60601-1-11	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 61233	IEC 60601-1 IEC60601-1-2 IEC 60601-1-11	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Conclusions

Air Compression Leg Massage is substantially equivalent to the primary predicate device and secondary predicate device.

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the subject device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-23, Biological evaluation of medical devices Part 23: Tests for skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Medical Electrical Equipment Part 1: 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

3) Battery Safety

- IEC 62133-2 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

4) Software Verification and Validation

Software documentation consistent with ***basic documentation level*** was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Air Compression Leg Massager is as safe, as effective, and performs as well as the primary predicate device and secondary predicate device.