November 20, 2024

Shenzhen Ruiyi Business Technology Co., Ltd.
℅ Libray Zhang
Official Correspondent
Shanghai Spica Management Consulting Co., Ltd.
609 Room, No.133 Shengang Avenue, Pudong New District
Shanghai, 201306
China

Re: K232965
Trade/Device Name: Leg Massager (Models: RP-ALM070H, RP-ALM071H)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IRT
Dated: September 30, 2024
Received: September 30, 2024

Dear Libray 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 (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K232965

Device Name
Leg Massager (Models:RP-ALM070H, RP-ALM071H)

Indications for Use *(Describe)*
Leg Massager (Models:RP-ALM070H, RP-ALM071H) is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health.

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.

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# K232965

**Type of Submission** Traditional

**Date Prepared** Jun 27, 2023

**Submission Sponsor**


| | |
|---|---|
| Manufacturer Name | Shenzhen Ruiyi Business Technology Co., Ltd. |
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| Tel | 86-18566621145 |
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**Application Correspondent**


| | |
|---|---|
| Company Name | Shanghai Spica Management Consulting Co., Ltd. |
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| Email | Libray@spicagloble.com |
| Contact Person | Libray Zhang |


**Device Identification**

| | |
|---|---|
| Trade Name | Leg Massager (Models:RP-ALM070H, RP-ALM071H) |
| Regulation Number | 21 CFR 890.5650 |
| Classification Name | Massager, Powered Inflatable Tube |
| Device Classification | Class II |
| Panel | Physical Medicine |
| Product Code | IRP |
| Previous Submissions | **None** |

**Indications for Use**

Leg Massager (Models:RP-ALM070H, RP-ALM071H) is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health.

**Device Description**

Leg Massager (Models:RP-ALM070H, RP-ALM071H) is consist of air pressure sensor, air pump, sleeves etc working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses. The compression massage direction is from limb end to body center by inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The sleeve works under the action of sensor and microprocessor.

Leg Massager (Models:RP-ALM070H, RP-ALM071H), in medical market, it has a sequential squeezing from distal to proximal, thus help to improve circulation to the treated areas.

**Predicate Device Information**

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| Sponsor | Shenzhen Dongjilian Electronics Co., Ltd. |
| Trade/Device Name | Air Compression Therapy Device |
| 510(K) number | K193354 |
| Regulation Number | 21 CFR 890.5650 |

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| Sponsor | Medella Health Limited |
| Trade/Device Name | FLOWpresso |
| 510(K) number | K223729 |
| Regulation Number | 21 CFR 890.5650 |

## Table 6A: Summary of Comparison

| | Subject Device | Predicate Device | Differences Discussion |
|---|---|---|---|
| Device name | Leg Massager (Models:RP-ALM070H, RP-ALM071H) | Air Compression Therapy Device | N/A |
| 510(k) number | K232965 | K193354 | N/A |
| Manufacturer | Shenzhen Ruiyi Business Technology Co., Ltd. | Shenzhen Dongjilian Electronics Co., Ltd. | N/A |
| Product regulation | 21 CFR 890.5650 | 21 CFR 890.5650 | Same |
| Classification name | Massager, Powered Inflatable Tube | Massager, Powered Inflatable Tube | Same |
| Regulation class | 2 | 2 | Same |
| Product code | IRP | IRP | Same |
| Indications for use | Leg Massager (Models:RP-ALM070H, RP-ALM071H) is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health. | 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. | Same |

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| Rx or OTC | OTC | OTC | Same |
| Pressure range | 0~240mmHg | 0~240mmHg | Same |
| Inflation Time | 3-30s | 3-30s | Same |
| Deflation Time | 1-5s | 1-5s | Same |
| Treatment time | 20 minutes | 20 minutes | Same |
| Standard | ES 60601-1;<br>IEC60601-1-2;<br>ISO 10993-5:<br>ISO 10993-10;<br>IEC 60601-1-11 | ES 60601-1;<br>IEC60601-1-2;<br>ISO 10993-5:<br>ISO 10993-10;<br>IEC 60601-1-11 | Same |
| Mode of compression | Sequential | Sequential/ Peristaltic | Same |
| Power source | 100~240V 50/60Hz | 100~240V 50/60Hz | Same |
| Power consumption | 24W | 12W | Similar |
| Size and appearance of sleeves (leg part) | Thighs:<br>One size: 11*16*24.9inch+8*33.5inch | Leg：<br>One size: 73*26cm | |

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| Photo | RP-ALM070H:<br>  <br>RP-ALM071H:<br>  |  | Similar |
| Housing materials | Molded ABS enclosure | Molded ABS enclosure | Same |
| Number of chambers | 3 | 3 | Same |
| Work mode | RP-ALM070H:<br>Six models (3 combine massage modes and 3 Separate Massage Modes)<br>C1: Massage full legs.<br>C2: Massage feet and calves.<br>(It can be used individually, and don’ t need | Mode 1:<br>Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the | Although the subject device provides 6 kinds of work mode, the Mode F1, F2, F3, M1, M2, M3 are the similar with predicate device (K193354), while the other work modes of subject device just have difference about inflatable order of the different chambers. The treatment pressure range are the |

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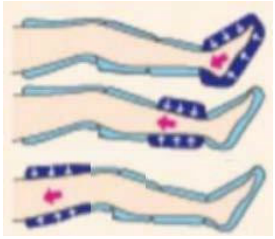
| | to connect the air hose of thighs wraps.)<br>C3: Massage feet, calves, thighs by turn. It will be turn off When you press the Button C again.<br>T: Massages thighs<br>C: Massages calves<br>F : Massages feet. It will be turn off when you press the Button S again.<br><br>RP-ALM071H:<br>Five models(3 combine massage modes and 2 Separate Massage Modes)：<br>Combine 1: Massage feet and calves<br>Combine 2: Massage from calves to feet<br>Combine 3: Massage from feet to calves. Press it again to turn off combine message function.<br>F: Massage feet.<br>C: Massage calves. Press it again to turn off separate massage function. | pre-determined air pressure level, then decompresses and the air pressure drops.<br>Once the thigh section decompresses, the cycle begins again.<br>Mode 1 follows this pressure sequence:<br>  <br>Mode 2:<br>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.<br>All three sections then decompress simultaneously and the air pressure drops, then cycle begins again.<br>Mode 2 follows this pressure | same under different work modes, so the difference of pressure range would not raise adversely impact on safety and effectiveness. |

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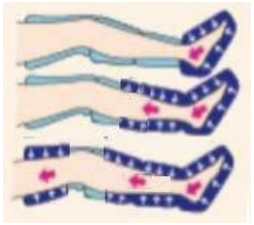
| | | sequence:<br>  <br>Mode 3:<br>include two stage, stage 1: it work according to the method of mode 1, after the stage 1 is completed, it go to stage 2(working according to the method of mode 2) without interruption time until finish the stage 2, then enter next cycle without interruption.<br>Mode1 ⇄ Mode2<br>The pressure sequence of mode 3 combines mode 1 and mode 2 | |
| Safety feature | 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 | Same |
| Technology | Compressor and valve system which sequentially inflates inflatable chambers | Compressor and valve system which sequentially inflates inflatable chambers | Same |

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| Operating environment | Temperature: 5℃- 40℃,<br>Humidity: 15%- 90% | Temperature: 5℃- 40℃,<br>Humidity:5%- 90%<br>non-condensing | Same |
| Transportation and Storage environment | Temperature: - 25℃~70℃<br>Humidity:15%-90% non condensing<br>Atmospheric Pressure:75kPa-106kPa | Temperature: - 20℃~55℃;<br>Humidity:5%-90% non condensing<br>Atmospheric Pressure:75kPa-106kPa | Similar |

## Table 6B: Summary of Comparison

| | Subject Device | Predicate Device | Differences Discussion |
|---|---|---|---|
| Device name | Leg Massager (Models:RP-ALM070H, RP-ALM071H) | FLOWpresso | N/A |
| 510(k) number | K232965 | K223729 | N/A |
| Manufacturer | Shenzhen Ruiyi Business Technology Co., Ltd. | Medella Health Ltd | N/A |
| Product regulation | 21 CFR 890.5650 | 21 CFR 890.5650 | Same |
| Classification name | Massager, Powered Inflatable Tube | Massager, Powered Inflatable Tube | Same |
| Regulation class | 2 | 2 | Same |
| Product code | IRP, IRT | IRP, IRT | Same |
| Indications for Use | Leg Massager (Models:RP-ALM070H, RP-ALM071H) is intended for home to temporarily relieve minor muscle aches | The Flowpresso Device combines heat and compression therapy. Flowpresso is intended to treat post | Similar, although the predicate device is intended to treat post traumatic and post-surgical medical and/or surgical |

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| | and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health. | traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy are indicated. Flowpresso is intended to be used by, or on the order of, licensed health care professionals based in rehabilitation facilities, outpatient clinics and athletic training settings. | conditions for which localized thermal therapy are indicated, the subject device is ,the working principles and expected outcomes of the two are consistent. All of them relieve pain by combining heat therapy with air compression on the affected area (subject device only covers the thighs, calves, and feet, predictive device also includes the back/hip), allowing patients to relax. |
| Number of patients that can be treated at one time | One | One | Same |
| Treatment Time | 20 minutes | 01-40 minutes | Different, Although the “Treatment Time” of the subject device is different than the predicate devices, the treatment time of the subject device is included in the predicate device. |
| Heat Therapy | Not exceeding 45°C | Default: 86°F – 104°F | Similar, the maximum temperature of the subject device is slightly higher than that of the predicate device. The heating program of the subject device can be selected to be turned on or not, and all have passed IEC testing. Small differences do not affect safety and effectiveness. |

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| Compression Pressure Levels | 0~240mmHg | 5-130mm/Hg | Different, pressure range is dependent on patient comfort levels and are adjusted in real-time. |
| Static or Intermittent Pressure | Both | Both | Same |
| Power Down | Available | Available | Same |
| Heating Mechanism | Thermotherapy | Thermotherapy | Same |
| User Interface | Touch Screen | Touch Screen | Same |
| Line voltage | 100~240V | 110-220V | Similar |
| Line Frequency | 50/60Hz | 50/60 Hz | Same |
| Electrical Safety Standards | ES 60601-1;<br>IEC60601-1-2;<br>IEC 60601-1-11 | ANSI/AAMI ES60601-1:2005 + A1:2012<br>IEC 60601-1:2005 + A1:2012<br>EN60601-1:2006 +A1:2013 | Similar |
| Operating Temperature | 5℃- 40℃ | 60°F – 80°F (16°C – 27°C) | Different, Although the “Operating Temperature” of the subject device is different than the predicate devices, they comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness. |
| Storage Temperature | - 25℃~70℃ | 33°F – 122°F (1°C - 50°C) | Different, Although the “Storage Temperature” of the subject device is different than the predicate devices, they comply with ANSI/AAMI ES60601-1, so |

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| | | | the difference does not affect the safety and effectiveness. |
| Operating Humidity | 15%- 90% | Below 60% Noncondensing | Different, Although the “Operating Humidity” of the subject device is different than the predicate devices, they comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness. |
| Storage Humidity | 15%-90% | Below 60% Noncondensing | Different, Although the “Storage Humidity” of the subject device is different than the predicate devices, they comply with ANSI/AAMI ES60601-1, so the difference does not affect the safety and effectiveness. |
| Operating Atmospheric Pressure and Altitude | 75kPa-106kPa | 700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft. 6 in (3000m)) | Similar |
| Types of Garments | Sleeves for thighs, calves, and feet | Various anatomical thermal/compression garments for: Back/Hip, arm, leg, feet | Different, the type of garments of the predicate device exceeds that of the subject device, which does not include the back/ip part. So the risk of subject device is smaller than that of predicate device. |
| Patient Contacting Material | All encompassed with a Nylon with a Polyurethane laminate material. | Needle cotton, non-conductive and non-woven lining. All encompassed with a PVC material. | Different, Although the material of the subject device is different than the predicate devices, they comply with ISO10993-5 and ISO10993-10, so the difference does not |

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| | | | affect the safety and effectiveness. |
| Multi-Patient Use and Single Patient Use Wraps | Multi-Patient Use | Multi-Patient Use | Same |
| Biocompatibility | Cytotoxicity testing per ISO 10993-5<br>Sensitization testing per ISO 10993-10<br>Irritation testing per ISO 10993-10 | Cytotoxicity testing per ISO 10993-5<br>Sensitization testing per ISO 10993-10<br>Irritation testing per ISO 10993-10 | Same |
| Sterile/Non Sterile | Non-sterile only | Non-sterile only | Same |
| Cleaning Disinfection Validation of Labeling | Yes- for Multi-Patient use reusable wraps | Yes- for Multi-Patient use reusable wraps | Same |
| Human Factors testing to confirm intended users have found instructions for cleaning and disinfection easy to use | Yes- for Multi-Patient use reusable wraps | Yes- for Multi-Patient use reusable wraps | Same |
| Expected Life of | Based on frequency of use and | Based on frequency of use and | Same |

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| Garments | continued functional performance | continued functional performance | |
| Validation of repeated cleaning and disinfection for reusable garments | Yes- for Multi-Patient use reusable wraps | Yes- for Multi-Patient use reusable wraps | Same |

**Summary of the technological characteristics of the device**

The device meets all the applicable technical requirements of :
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
IEC 60601-1-2: 2014 - Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC TS 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ISO 10993-5: 2009 - Biological Evaluation of Medical Device - Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10: 2010 - Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization

**Conclusion**

Based on the indications for use, technological characteristics, and non-clinical performance data, “Leg Massager (Models:RP-ALM070H, RP-ALM071H)” is as safe, as effective, and performs as well as the legally marketed predicate devices. Therefore, the subject device is substantially equivalent to the predicate device.