April 25, 2025

Shenzhen Urion Technology Co., Ltd.
Janice Ou
Official Applicant
Fl 4-6th of Bldg D, Jiale Science & Technology Indust Zn,No3
Chuang Wei Rd., Heshuikou Community, MaTian St, GuangMing NewDi
Shenzhen, Guangdong 518106
China

Re: K250046
Trade/Device Name: Air Compression Leg Massager (UM605, UM606, UM607, UM608,UM609,UM610, UM611, UM617)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 25, 2025
Received: March 12, 2025

Dear Janice Ou:

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,

Julia E. Slocomb -S 2025.04.25 15:59:21 -04'00'

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K250046

Device Name

Air Compression Leg Massager (UM605, UM606, UM607, UM608，UM609，UM610, UM611, UM617)

Indications for Use *(Describe)*

The Air Compression Leg Massager is used to temporarily relieve mild muscle pains and discomfort, and temporarily increase blood circulation to the treatment 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.**

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
# K250046

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

## 1 Administrative Information

| | |
|---|---|
| **Submission Date** | Dec. 30th, 2024 |
| **Manufacturer information** | Submitter's Name: Shenzhen Urion Technology Co.,Ltd<br>Address: Floor 4-6th of Building D, Jiale Science & Technology Industrial Zone, No.3, Chuang Wei Road, Heshuikou Community, MaTian Street, GuangMing New District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA<br><br>Contact person: Joanna Guo<br>TEL: (+86) -755-29231308<br>FAX: (+86) -755-29231308<br>E-Mail: Joanna@urionsz.com |
| **Submission Correspondent** | Contact person: Miss Janice Ou<br>E-Mail: 411070313@qq.com |

## 2 Device Information

| | |
|---|---|
| **Common name of the device** | Powered inflatable tube massager |
| **Trade name of the device** | Air Compression Leg Massager |
| **Type/Model of the device** | UM605, UM606, UM607, UM608, UM609, UM610, UM611, UM617 |
| **Classification information** | Classification panel: Physical Medicine<br>Classification name: Massager, Powered Inflatable Tube<br>Regulation Number: 890.5650<br>Device Class: II<br>Product Code: IRP |
| **type of 510(k) submission** | Traditional |

## 3 Predicate Device Information

| | |
|---|---|
| **Sponsor:** | Xiamen Emoka Health Science & Technology Co., Ltd. |
| **Device:** | Air Compression Leg Massager |
| **510(K) Number:** | K222991 |

## 4 Device Descriptions

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.

The models include UM605, UM606, UM607, UM608 , UM609 , UM610, UM611, UM617. All of them have same Indications for use, technological characteristics and similar device appearance. And they have the same electrical circuit design, PCB layout, critical components and internal wiring. The differences for them are software function, operation method for mode adjustment and the shape of compatible inflatable garment.

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 the main body. The main body and the inflatable garment are not detachable.

Function buttons and light emitting diode (LED) indicators on the main body make up the user interface. Each inflatable garment is connected to the main body by air hoses and encase a 2-chamber air bladder inside. Calves can be wrapped and massaged separately by the two chambers. The main unit is directly installed on the inflatable garment through tubes and fixing buckles, and there is no need for users to install it again.

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 main body controls the inflating and deflating of the air bladders according to preset program.

## 5 Intended Use/ Indications for Use

This Air Compression Leg Massager is used to temporarily relieve mild muscle pains and discomfort, and temporarily increase blood circulation to the treatment areas in people who are in good health. Air Compression Leg Massager simulates kneading and stroking of tissues by using an inflatable garment.

## 6 SE Comparison

**Table 1. Substantial Equivalence Comparison**

| Items | Subject Device | Predicate Device (K222991), | Remarks |
|---|---|---|---|
| **Product name** | Air Compression Leg Massager | Air Compression Leg Massager | / |
| **Classification name** | Powered inflatable tube massager | Powered inflatable tube massager | / |
| **Product code** | IRP | IRP | / |
| **Intended use** | This Air Compression Leg Massager is used to temporarily relieve mild muscle pains and discomfort, and temporarily increase blood circulation to the treatment 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. | Same |
| **Indications for use** | Same for intended use. | Same for intended use. | Same |
| **Device Models** | UM605, UM606, UM607, UM608, UM609, UM610, UM611, UM617 | EMK 701 | / |
| **Manufacturer** | Shenzhen Urion Technology Co., Ltd | Xiamen Emoka Health Science & Technology Co., Ltd. | / |
| **Power source** | Internal Rechargeable Lithium Battery: DC 3.7V, 2000mAh<br>Output voltage of adapter: 5V ± 5%; output current: 600 mA | Input: AC100-240V, 50/60Hz<br>Output: DC 13.5V, 1A<br>Internal battery: 11.1V, 1000mAh | Different (**Note01**) |
| **Dimensions(W*H*D)** | 126mm x 68mm x26mm | 215*50*70 mm | Different (**Note02**) |
| Photo |  |  | |
| Weight | 370g | 2.0 Kg (4.4pounds) | |
| Housing Materials | Molded ABS enclosure | Molded ABS enclosure | Same |
| Sleeves Dimensions | Sector Leg Wrap:633*304mm | Leg Wrap: 730*468 mm | Different (**Note02**) |

| Items | Subject Device | Predicate Device (K222991), | Remarks |
|---|---|---|---|
| |  <br>Arced Leg Wrap:615*320mm<br>  |  | |
| Application area | Leg(calves) | Leg (feet, calves) | SE (**Note03**) |
| Number of Chambers | 2-chamber | 2-chamber | Same |
| Sleeve Materials | Poly(ethylene terephthalate)(PET) | Dacron | Same<br>Dacron is the trade name of PET. |
| Mode of Compression | Sequential | Sequential | Same |
| Air Pressure Level | Low level: 120mmHg<br>Medium level: 170mmHg<br>High level: 210mmHg<br>Error range: ±25mmHg | Low level: 120mmHg<br>Medium level: 170mmHg<br>High level: 210mmHg<br>Error range: ±25mmHg | Same |
| Timer setting for treatment Time | 15min, 30min, 45min | 15 min | Similar (**Note04**) |
| Inflation time | 5-10 s | 5-18 s | Same |
| Keep time | 2 - 5 s | 2 - 5 s | Same |
| Deflation time | 2–5 s | 2–5 s | Same |
| Work Mode | There's a working Mode:<br>The two chambers are inflated and deflated at the same time.<br>Mode follow s this pressure sequence:<br>Calf → Interval → Calf<br>The inflating and deflating time are different according to the intensity selected. | Mode 1:<br>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 is compressed. Then calf chamber deflates, and finally foot chamber deflates. The third process is starting with calf chamber inflates and deflates then.<br>Mode 1 follow s this pressure sequence: Foot → Foot + Calf → Interval → Foot → Foot + Calf → Foot → Interval → Calf<br>Mode 2:<br>In this model, foot chamber and calf | SE (**Note05**) |

| Items | Subject Device | Predicate Device (K222991), | Remarks |
|---|---|---|---|
| | | chamber are inflated and deflated at the same time.<br>Mode 2 follow s this pressure sequence: Foot + Calf → Interval → Foot + Calf<br>The inflating and deflating time are different according to the intensity selected. | |
| Noise level | < 55dB | ≤ 65 dB | Similar (**Note06**) |
| Patient contact | Non-conductive appliances | Non-conductive appliances | Same |
| Software/Firmware/ Microprocessor Control | Microprocessor | Microprocessor | Same |
| Technology | Compressor and valve system which sequentially inflates cells of appliance | Compressor and valve system which sequentially inflates cells of appliance | Same |
| Safety Features | Power button allow s user to stop therapy session at any time | Power button allow s user to stop therapy session at any time | Same |
| Operating environment | Temperature: 5℃-40℃,<br>Humidity: 15%~93% RH without condensation,<br>Atmospheric conditions : 86 kPa ~ 106 kPa | Temperature: 5℃-40℃<br>Humidity: 5%- 90% noncondensing | Similar (**Note07**) |
| Transportation &Storage environment | Temperature: -20℃ to + 55℃,<br>Humidity: 15%~93% RH without condensation<br>Atmospheric conditions : 86 kPa ~ 106 kPa | Temperature: -20℃~55℃<br>Humidity: 5%-90% noncondensing<br>Atmospheric Pressure: 75-106kPa | |
| Electrical safety, EMC | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 62133-2 | ANSI/AAMI ES60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 62133 | Same |
| Biocompatibility | ISO 10993-5<br>ISO 10993-10<br>ISO 10993-23 | ISO 10993-5<br>ISO 10993-10 | SE |

**Note 01:**
The power supply is different from subject device, it is supplied by internal rechargeable Lithium Batter. Battery both of them are complied with the 60601-1 standard. This difference will not affect the safety and effectiveness.

**Note 02:**
The physical parameters (dimensions, appearance,) have minor differences with predicate device. They will not affect the safety and effectiveness of the subject device.

**Note 03:**

The application area of subject device is covered in predicate device. It will not affect the safety and effectiveness of the subject device.

**Note 04:**

Both the predicate and the subject device have no restriction on number of treatments in a day. However, we suggest to rest 30 minutes before starting another treatment session. The proposed device just offers three timing settings, which are more convenient for patients to use, while the predicate only has one time setting.

**Note 05:**

The subject device has only one working mode, and it is substantially equivalent to the second working mode 2 of the predicate device. The application site of the subject device only includes the calf, while that of the predicate device includes both the calf and the feet. Therefore, for the treatment of the calf, the working mode of the subject device is substantially equivalent to that mode 2 of the predicate device.

**Note 06:**

The acceptance criteria of subject device is included in predicate device. It will not raise any safety and effectiveness issue of the subject device.

**Note 07:**

The operating condition and the transportation &storage environment of subject device has passed the safety test, and the Instructions for Use provides the operating condition, so the difference in operating condition between subject device and predicate device will not affect the safety and effectiveness of subject device.

## 7 Brief discussions of the non-clinical tests

**Performance testing:**

The subject device conforms to the following guidances and 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 requirement for basic safety and essential performance-Collateral standard: Electromagnetic compatibility –Requirements and tests
- 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
- 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

**Biocompatibility testing:**

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process ". The biocompatibility testing includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation

## 8 Brief discussions of clinical tests

No Clinical Test conducted.

## 9 Other information (such as required by FDA guidance)

No other information.

## 10 Conclusions

The subject device: Air Compression Leg Massager manufactured by Shenzhen Urion Technology Co., Ltd is substantially equivalent to the predicate device (K222991).