U.S. FOOD & DRUG ADMINISTRATION

May 5, 2026

Wenzhou Lingfeng Electronic Technology Co., Ltd.
% Reanny Wang
General manager
Shenzhen Reanny Medical Devices Management Consulting Co., Ltd
Rm. 1509, Jingting Bldg., Dongzhou Community
Guangming St., Guangming District
Shenzhen, Guangdong 518107
China

Re: K254200
Trade/Device Name: Air Compression Leg Massager (LF-FT001, LF-FT002-1, LF-FT003, LF-FT003-1, LF-FT004-1, LF-FT005-1, LF-FT006-1, LF-FT007, LF-FT008, LF-FT009, LF-FT010, LF-FT011, LF-FT012, LF-FT013, LF-FT014, LF-FT015, LF-FT016, UM-01, UM-02, UM-03, UM-03-1, UM-04-1, UM-05-1, UM-06-1, UM-07, UM-08, UM-09, UM-10, UM-11, UM-12, UM-13, UM-14, UM-15, UM-16, AI-01, AI-02, AI-03, AI-04, AI-05, AI-06, AI01, AI02, AI03, AI-07, AI-08, AI-09, AI-10, AI-11, AI-12, AI-13, AI-14)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: December 22, 2025
Received: December 29, 2025

Dear Reanny Wang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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.	K254200

Please provide the device trade name(s).

Air Compression Leg Massager (LF-FT001, LF-FT002-1, LF-FT003, LF-FT003-1, LF-FT004-1, LF-FT005-1, LF-FT006-1, LF-FT007, LF-FT008, LF-FT009, LF-FT010, LF-FT011, LF-FT012, LF-FT013, LF-FT014, LF-FT015, LF-FT016, UM-01, UM-02, UM-03, UM-03-1, UM-04-1, UM-05-1, UM-06-1, UM-07, UM-08, UM-09, UM-10, UM-11, UM-12, UM-13, UM-14, UM-15, UM-16, AI-01, AI-02, AI-03, AI-04, AI-05, AI-06, AI01, AI02, AI03, AI-07, AI-08, AI-09, AI-10, AI-11, AI-12, AI-13, AI-14)

Please provide your Indications for Use below.

The Air Compression Leg Massager is intended for home use 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.

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

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

K254200

510(k) Summary

Type of 510(k) submission: Traditional

Date prepared: Apr.11, 2026

Applicant's information:

Applicant Name	Wenzhou Lingfeng Electronic Technology Co., Ltd.
Applicant Address	No.6 Puxi Industry Zone, Tongpu, Ruian, Zhejiang 325216 China
Applicant Contact Telephone	86-577-65436666
Applicant Contact	Ms. Xiaoqun Ye
Applicant Contact Email	lingfeng@bwell-cn.com

Correspondent's information:

Correspondent Name	Shenzhen Reanny Medical Devices Management Consulting Co.,Ltd.
Correspondent Address	Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District Shenzhen Guangdong 518107, China
Correspondent Contact Telephone	86-755-27391220
Correspondent Contact	Mr. Reanny Wang
Correspondent Contact Email	reanny@reanny.com

Device Identification:

Device Trade Name	Air Compression Leg Massager (Models: LF-FT001, LF-FT002-1, LF-FT003, LF-FT003-1, LF-FT004-1, LF-FT005-1, LF-FT006-1, LF-FT007, LF-FT008, LF-FT009, LF-FT010, LF-FT011, LF-FT012, LF-FT013, LF-FT014, LF-FT015, LF-FT016, UM-01, UM-02, UM-03, UM-03-1, UM-04-1, UM-05-1, UM-06-1, UM-07, UM-08, UM-09, UM-10, UM-11, UM-12, UM-13, UM-14, UM-15, UM-16, AI-01, AI-02, AI-03, AI-04, AI-05, AI-06, AI01, AI02, AI03, AI-07, AI-08, AI-09, AI-10, AI-11, AI-12, AI-13, AI-14)
Common Name	Air Compression Leg Massager
Classification Name	Massager, Powered Inflatable Tube
Regulation Number	21 CFR 890.5650
Product Code(s)	IRP, IRT
Regulatory Class	II

Predicate Device Information:

Sponsor	Shenzhen Ruiyi Business Technology Co.,Ltd.
Trade/Device Name	Leg Massager (Models:RP-ALM070H, RP-ALM071H)
510(k)Number	K232965
Regulation Number	21 CFR 890.5650

Indications for use:

The Air Compression Leg Massager is intended for home use 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:

The Air Compression Leg Massager consists of one controller, one adapter and two leg sleeves working together as one unit. The two sleeves shall be connected to the controller while using. Each sleeve contains 3 air chambers, namely for the thigh, calf and foot. In different modes, it can provide massages for different body sites. It also provides heating functions for the feet and knees. The pressure and heating temperature can be adjusted with 3 levels to avoid any discomfort to the patient, and the heating function can be turned off independently. The sleeves works under the action of the controller to control the pressure and the heating temperature. The air pump in it applies periodic pressure changes to the peripheral blood and tissues of the leg, thus help to temporarily relieve muscle aches and pains and improve circulation of the treated areas.

Substantial Equivalence Discussion

Device	Subject device	Primary Predicate device	Comparison
Manufacturer	Wenzhou Lingfeng Electronic Technology Co., Ltd.	Shenzhen Ruiyi Business Technology Co., Ltd.	NA
510(K) number	Pending	K232965	NA
Product name	Air compression leg massager (Model No.: LF-FT001, LF-FT002-1, LF-FT003, LF-FT003-1, LF-FT004-1, LF-FT005-1, LF-FT006-1, LF-FT007, LF-FT008, LF-FT009, LF-FT010, LF-FT011, LF-FT012, LF-FT013, LF-FT014, LF-FT015, LF-FT016, UM-01, UM-02, UM-03, UM-03-1, UM-04-1, UM-05-1, UM-06-1, UM-07, UM-08, UM-09, UM-10, UM-11, UM-12, UM-13, UM-14, UM-15, UM-16, AI-01, AI-02, AI-03, AI-04, AI-05, AI-06, AI01, AI02, AI03, AI-07, AI-08, AI-09, AI-10, AI-11, AI-12, AI-13, AI-14)	Leg Massager (Models: RP-ALM070H)	NA
Product Regulation	21 CFR 890.5650	21 CFR 890.5650	Same
Regulatory Class	2	2	Same
Product code	IRP, IRT	IRP, IRT	Same
OTC or Rx	OTC	OTC	Same
Indications for Use (IFU)	The Air Compression Leg Massager is intended for home use 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.	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.	Same

Device	Subject device	Primary Predicate device	Comparison
Device photo			Similar Both devices are composed of 2 leg sleeves and 1 controller. The sleeves are connected to the controller via air hoses. The difference will not affect the safety and effectiveness of the device.
Number of chambers	3	3	Same
User interface	Buttons and LCD	Touch screen	Different, but the difference will not affect the safety and effectiveness of the device. The illustration of user interface has been provided in the user manual.
Pressure range	0-31 kPa (0-232.5 mmHg)	0-240 mmHg	Similar Note 1
Inflation time	0.6-13s	3-30s	Different Note 9
Deflation time	0.4-12s	1-5s	Different Note 9
Treatment time	20 minutes	20 minutes	Same
Mode of compression	Sequential/ Peristaltic	Sequential	Different Note 2
Static or Intermittent Pressure	Both	Both	Same

Device	Subject device	Primary Predicate device	Comparison
Size of sleeves	Calf Circumference: min. 14cm, max. 23cm; Upper Thigh Circumference: min. 21.5cm, max. 37.5cm; Lower Thigh Circumference: min. 16cm, max. 30cm.	Thighs part: One size: 11*16*24.9 inch + 8*33.5 inch	Different Note 3
Intended Use Environment	Home healthcare environment	Home healthcare environment	Same
Power Source(s)	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	Same
Power consumption	24W	24W	Same
Technology	Compressor and valve system which sequentially and peristalticly inflates inflatable chambers.	Compressor and valve system which sequentially inflates inflatable chambers.	Same
Working modes	3 modes. Mode 1: foot→calf & thigh→all Mode 2: calf & thigh Mode 3: calf & thigh→foot→all	RP-ALM070H: Six modes (3 combine massage modes and 3 Separate Massage Modes) C1: Massage full legs. C2: Massage feet and calves. (It can be used individually, and don't need to connect the air hose of thighs wraps.) C3: Massage feet, calves, thighs by turn. It will be turn off When you press the Button C again. T: Massages thighs C: Massages calves F : Massages feet. It will be turn off when you press the Button S again.	Different Note 4

Device	Subject device	Primary Predicate device	Comparison
Safety features	The user can turn off the device at any time by pressing button on the device, or disconnect the sleeves by detaching the hoses of the sleeves from the controller, thereby stopping the treatment.	Button on display allows user to stop or pause therapy session at any time	Similar Both devices can stop the treatment at any time. The difference will not affect the safety and effectiveness of the device.
Operating environment	Temperature: 5℃ to 40℃ ; Humidity :15%-90% RH; Atmospheric Pressure : 70 kPa to 106 kPa	Temperature: 5℃- 40℃, Humidity: 15%- 90%	Same
Transportation and storage environment	Temperature: -25℃ to 50℃; Humidity: 15%-90% RH; Atmospheric Pressure: 70 kPa to 106 kPa; Keep dry and avoid direct sunlight exposure.	Temperature: - 25℃-70℃ Humidity:15%-90% non condensing Atmospheric Pressure:75kPa-106kPa	Similar, Note 10
Pressure Levels	3 levels each mode	3 levels each mode	Same
Heating sites	Knees and feet	Calves and feet	Different Note 5
Heating temperature	Not exceeding 43 ℃	Not exceeding 45 ℃	Simiar Note 6
Heating mechanism	Thermotherapy	Thermotherapy	Same
Patient contacting material	Nylon	All encompassed with a Nylon with a Polyurethane laminate material.	Similar Note 7
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Same
Multi-patient use or single-patient use	Multi-patient use	Multi-patient use	Same

Device	Subject device	Primary Predicate device	Comparison
Sterility	Non-sterile	Non-sterile	Same
Cleaning Disinfection Validation of Labeling	Yes- for Multi-Patient use reusable wraps	Yes- for Multi-Patient use reusable wraps	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 Garments	Based on frequency of use and continued functional performance	Based on frequency of use and continued functional performance	Same
Validation of repeated cleaning and disinfection for reusable garments	Yes- for Multi-Patient use reusable wraps	Yes- for Multi-Patient use reusable wraps	Same
Electrical safety standards	IEC 60601-1+US national differences IEC 60601-1-2	ES 60601-1 IEC 60601-1-2	Similar The subject device has been

Device	Subject device	Primary Predicate device	Comparison
	IEC TS 60601-4-2 IEC 60601-1-11	IEC 60601-1-11	subject to the test of latest applicable standards. The difference will not affect the safety and effectiveness.
Biocompatibility tests	ISO 10993-5: 2009 In vitro cytotoxicity ISO 10993-10: 2021 Skin sensitization ISO 10993-23: 2021 Irritation	Cytotoxicity testing per ISO 10993-5 Sensitization testing per ISO 10993-10 Irritation testing per ISO 10993-10	Different Note 8.

Comparison discussion:

Note 1:

The pressure range of the subject device falls within the pressure range of the predicate device, and the difference is minimal. The safety of the subject device has been verified according to IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11, and its performance has been verified through performance testing. Therefore, this difference will not affect the safety or effectiveness of the subject device.

Note 2:

The subject device has two compression modes: Sequential and Peristaltic, while the predicate device only has the Sequential mode. In sequential mode, the air chambers inflate in a specific order, and once inflated, they remain inflated. In peristaltic mode, some airbags deflate while others inflate, simulating a massaging effect. Both modes have been evaluated in previous SE discussion of devices on the market and have not been assessed as posing impact on safety or effectiveness.

Besides, the treatment areas of the subject device and the predicate device both include the foot, calf, and thigh, and the pressure ranges are essentially the same. Therefore, this difference will not affect safety or effectiveness of the subject device.

Note 3:

The size of the sleeves does not affect the safety or effectiveness of the product. The leg sleeves have a Velcro design, allowing users to adjust the size themselves for a better fit around the leg. And an extension pad is provided to the user to prevent issues related to improper fit.

Note 4:

The predicate device can provide massage to the feet, calves, or thighs individually, whereas the subject device only offers massage to the entire leg or the thighs & calves combined. However, the general massaging areas of both devices are the legs and feet, and the two devices' pressure ranges are essentially consistent, so this difference does not affect the safety or effectiveness of the device.

Note 5 and Note 6:

The heating area of the subject device excludes the calf but includes the knee. The specific heating temperature of the predicate device has not been disclosed, but the heating temperature of the subject device falls within the range of the predicate device, and the difference in maximum temperature is minimal. Furthermore, the temperature accuracy of the subject device has been verified through performance testing, and the safety of the subject device has been verified according to IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11, so this difference does not affect the safety or effectiveness of the device.

Note 7 and Note 8:

The materials used in the subject device are commonly employed in the industry. The biological safety of these materials has been verified through biocompatibility testing in accordance with the ISO 10993 series of standards. Therefore, the difference in materials will not affect the safety and effectiveness of the device.

Exposure to the device can result in a localized nonspecific inflammatory response which can lead to redness, swelling, itching, dryness, cracking of the skin, blistering or pain.Therefore, we selected the more stringent intradermal reaction test as the irritation test instead of the skin irritation test. The test results indicate that the materials of the subject device do not cause any intradermal reactions, which means the biocompatibility of the subject device's materials is at least comparable to that of the predicate device.

Note 9:

Although the inflation and deflation times of the subject device are different from those of the predicate device, the final output pressure values and the whole treatment time of the two devices are equivalent. Also, the safety of the subject device has been verified according to IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11, and its performance has been verified through performance testing. Therefore, this difference will not affect the safety or effectiveness of the subject device.

Note 10:

The subject device has some differences in terms of temperature and atmospheric pressure limits for transportation and storage compared to the predicate device, but it has been verified by the test of IEC 60601-1-11 that the subject device can operate within its specified normal use after transport or storage in the specified environmental conditions. Therefore, this difference will not affect the safety or effectiveness of the subject

device.

Performance Data

The following performance data were provided in support of the substantial equivalence determination, demonstrating that the proposed device complies with the following standards.

1) Electrical safety and electromagnetic compatibility

   IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

   IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

   IEC 60601-1-11:2015+A1:2020 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

2) Software verification and validation testing

   Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance - Content of Premarket Submissions for Device Software Functions. The software documentation level for this device was considered ‘enhanced’.

3) Biocompatibility testing

   10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

   10993-10 Fourth edition 2021-11 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization

   10993-23 First edition 2021-01 - Biological evaluation of medical devices - Part 23: Tests for irritation

4) Bench performance testing included pressure accuracy, heating validation, inflation sequence, and safety function testing per the manufacturer’s protocol.

Conclusion:

The subject device has the same indications for use and similar technological characteristics as the predicate device. Although there are several specifications that are different between these devices, testing and discussion have been completed to demonstrate that the

differences between these parameters would not affect the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and all the results conform to the requirements. Therefore, the differences between the subject device and the predicate device do not raise any concerns with respect to substantial equivalence. The subject device is substantially equivalent to the predicate device and the differences in technological characteristics do not raise different questions of safety and effectiveness based on the testing submitted to support this submission.