July 24, 2026

Wavepulse (Xiamen) Healthcare TechnologyCo., Ltd.
℅ Ariel Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai, 200122
China

Re: K260948
Trade/Device Name: Air Compression Massager (EP30B001 I)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 22, 2026
Received: June 23, 2026

Dear Ariel 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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.07.24
11:15:47 -04'00'

for 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

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)*

K260948

Device Name

Air Compression Massager (EP30B001 I)

Indications for Use *(Describe)*

Air Compression Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary
K260948

Prepared on: 2026/06/15

A. Applicant

Wavepulse (Xiamen) Healthcare Technology, Co., Ltd.
Address：5/F-1,881 Tonglong 2nd Rd, Xiangan District, Xiamen Torch Hi-Tech Park, Xiamen, Fujian, China
Contact Person: Wang jie
Tel:+86 151 5965 9100
Mail: wangjie@wavepulse-med.com.cn

B. Subject Device

Device Name: Air Compression Massager
Model(s): EP30B001 I
Classification Name: Powered inflatable tube massager
Review Panel: Physical Medicine
Product Code: IRP
Regulation Number: 21 CFR 890.5650
Regulation Class: II

C. Predicate Device

Trade/Device Name: Air Compression Therapy Recovery System （MF-AWI, MF-AWI.LED.A801,MF-AWI.LED.B-801,MF-AWI.OLED.A-601,MFAWI.LED.A-601,MFAWI.LED.B-601,MFAWI.OLED.A-401,MFAWI.LED.A-401,MFAWI.LED.B-401）
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
510(k) Number: K230500

D. Device Description

Air Compression Massager: A powered inflatable massage device designed to mimic the effects of manual massage, providing temporary relief for minor muscle discomfort and enhancing local circulation.

The Air Compression Massager includes a control unit, an air three - way hose and a leg cuff with 5 chambers. The Leg cuff connects to the control unit through an air three - way hose. Users can freely choose to be configured with either a single leg cuff or two leg cuffs according to their preference.

The cuffs are made of Nylon cloth and thermoplastic polyurethane (TPU) and are available in black. The control unit is made of PC and ABS.

The Air Compression Massager is charged using an external compliant power adapter as well as powered by an internal IEC 62133-2 compliant lithium-ion battery.

E. Indication for use

Air Compression Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.

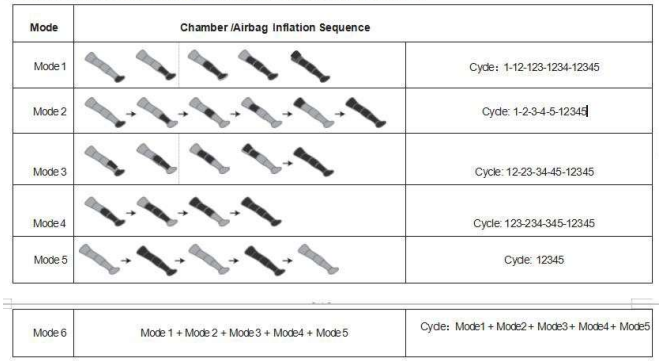
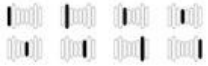
F. Comparison to predicate device

Item	Proposed device	Predicate Device	Discussion
Device name	Air Compression Massager	Air Compression Therapy Recovery System	-
Model	EP30B001 I	MF-AWI, MF-AWI.LED.A801, MF-AWI.LED.B-801, MF-AWI.OLED.A-601,MFAWI.LED.A-601,MFAWI.LED. B-601,MFAWI.OLED.A-401,MFAWI.LED.A-401,MFAWI .LED.B-401)	-
510(k) number	K260948	K230500	-
Manufacturer	Wave pulse (Xiamen) Healthcare TechnologyCo., Ltd.	Jiangsu MaxF Electric Appliance Co., Ltd	-
Product regulation	21 CFR 890.5650	21 CFR 890.5650	Identical
Classification name	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Identical
Regulation class	2	2	Identical
Product code	IRP	IRP	Identical
Indication for use	Air Compression Massager is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.	The Air Compression Therapy Recovery System (model: MF-AWI, MF-AWI.LED.A-801, MFAWI.LED.B-801, MFAWI.OLED.A-601, MFAWI.LED.A-601, MFAWI.LED.B-601, MFAWI.OLED.A-401, MFAWI.LED.A-401, MFAWI.LED.B-401) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas. The Air Compression Therapy Recovery System simulates kneading and stroking of tissues by using an inflatable	Identical

		garment. This device is Over-The-Counter (OTC). It is intended for use by healthy adults who are over 21 years old.	
Rx or OTC	OTC	OTC	Identical
Intended user	Adult	Adult	Identical
Environment of use	Clinics, hospital, athletic,training, and home environments.	Clinics, hospital, athletic,training, and home environments.	Identical
Power source	Adapter，Input：100-240V AC, 50/60Hz,1.5A； Output：15.0VDC，3.0A；	100-240V, 50/60Hz	Minor different, NOTE1
Power consumption	90W	30W	Minor different, NO TE1
Treatment time	Default 15,30 and 45minutes	0-50mins	Identical. The treatment time falls within the range of the predicate device.
Number of Chambers	5	4,6,8	Different; see Note 2.
Size and Photo		 140mm x 87mm x 280mm	Minor different, NOTE1

	259mm x 110mm x 90mm		
Weight	5.2kg	Not disclosed	Minor different,NO TE1
Housing materials	Molded ABS and Polycarbonate (PC) enclosure	Molded ABS enclosure	Minor different, NOTE2
Leg Sleeves	Leg	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower lack) Arm (including of entire arm, shoulder, upper chest and back)	Different. The subject device includes leg sleeves only, whereas the predicate device also includes hip/pants and arm sleeves. The subject device therefore has a narrower accessory scope. See Note 2.

Leg Attachment Photos and size		 1060mm x 345mm	Minor difference. ,NOTE 2
Sleeve Materials	Nylon and TPU	TPU Nylon Composite	Identical.
Pressure range	60-200mmHg; (60-80-110-130-150-170-200 mmHg)	20-200 mmHg (0-40-80-120-160-200mmHg)	Identical The pressure range is within the predicate device range.
Mode of compression	Sequential	Sequential	Identical

Work mode/ Treatment Mode	** The black color represents the number of working air chambers.*  	Mode of MF-AWI is listed as below: **Mode A: Pressure fills one chamber at a time and that chamber deflates while next chamber fills.** When the first chamber inflates to the selected pressure, the second chamber begins to inflate and the first chamber deflates. When the second chamber fully inflates, the third chamber begins to inflate and the second chamber deflates. Then the fourth, fifth, sixth, seventh and eighth inflate and deflate one by one.  **Mode B:** Pressure fills one chamber at a time. Each chamber remains inflated while the next one fills until all 8 chambers are inflated. Then, all the 8 chambers deflate together and the cycle repeats.  **Mode C: Pressure fills two chambers at a time and those two chambers deflate while the next two chambers fill.** The first and the second chambers inflate to the selected pressure at the same time. When	**Similar** NOTE3

		chambers one and two are fully inflated, the third and the fourth chamber begin to inflate while the first and the second chambers begin to deflate. The cycle repeats through the 8 chambers.  **Mode D: Pressure fills two chambers at a time until all 8 are filled**. The first and the second chambers inflate to the selected pressure. Once fully inflated, the third and the fourth chambers begin to inflate until all 8 chambers are fully inflated. Then, all the 8 chambers deflate together and the cycle repeats.  For MF-AWI.OLED.A-601 and MF-AWI.OLED.A-401 using 6 chambers and 4 chambers, the mode is the same as mode of MF-AWI as demonstrated above. For MF-AWI.LED.B-801,MF-AWI.OLED.A-601,MF-AWI.LED.A-601,MF-AWI.LED.B-601, MF-AWI.LED.A-401,MF-AWI.LED.B-401 They only has one mode (mode B).	 **Mode E: Pressure fills one chamber at a time and that chamber deflates while next chamber fills.** When the first chamber inflates to the selected pressure, the third chamber begins to inflate and the first chamber deflates. When the third chamber fully inflates, the fifth chamber begins to inflate and the third chamber deflates. Then the seventh, second, fourth, sixth and eighth inflate and deflate one by one.	

Software / Firmware Micro-processor or Control	Microprocessor	Microprocessor	Identical
Safety feature	Button on display allows user to stop or pause therapy session at any time	Button on control unit allow users to stop or pause therapy session at any time	Identical
Technology	Compressor and valve system which sequentially inflates inflatable chambers.	Compressor and valve system which sequentially inflates inflatable chambers.	Identical
Cycle Time	Run in mode	Not disclosed	Different, NOTE3
Treatment Area	Leg (including of foot, calf, knee, upper leg)	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower lack) Arm (including of entire arm, shoulder, upper chest and back)	Different. The subject-device treatment area is a subset of the predicate treatment areas and does not introduce a new anatomical site.

Photo/size of the pants	Not included in the final subject-device configuration.	 530mm x 730mm	Different. The subject device does not include a pants/hip sleeve. Its narrower accessory and treatment-area scope does not raise new questions of safety or effectiveness.

NOTE 1:

The subject device has a rated power consumption of 90 VA, compared with 30 W for the predicate device. This difference reflects the electrical design of the control unit and power supply and does not increase the maximum pneumatic pressure delivered to the user, which remains 200 mmHg. The subject device uses the same basic technology of an electronically controlled compressor and valves. Electrical safety, thermal, pressure-accuracy, and overpressure/fault testing demonstrated acceptable performance. Therefore, the differences in rated power consumption and device dimensions do not adversely affect the safety or effectiveness of the subject device.

NOTE 2:

The subject device uses five chambers in each leg sleeve, whereas the predicate-device family includes four-, six-, and eight-chamber

configurations. All configurations use the same basic technological principle of electronically controlled sequential pneumatic compression, and the subject device has the same maximum pressure of 200 mmHg as the predicate device.

The final five-chamber subject-device configuration was used for the applicable pressure-accuracy, inflation and deflation, fatigue, seam-strength, biocompatibility, fault-mode, and overpressure-protection evaluations. The subject device is limited to leg sleeves and therefore has a narrower garment and treatment-area scope than the predicate device. The nylon and TPU materials used in the subject-device sleeves are comparable to the TPU/nylon composite materials used in the predicate device and have been evaluated in accordance with the applicable ISO 10993 standards.

Therefore, the differences in chamber count, garment configurations, dimensions, and materials do not raise different questions of safety or effectiveness.

Note 3:

The subject device provides six treatment modes. Modes 1 through 5 use different selections, groupings, and distal-to-proximal inflation sequences of the same five chambers, while Mode 6 combines Modes 1 through 5. These modes do not change the type of energy delivered, the intended use, the anatomical treatment area, or the maximum pressure of 200 mmHg.

In every mode, the pressure remains within the selectable range of 60 to 200 mmHg, treatment duration is limited to 15, 30, or 45 minutes, and the user can pause or stop treatment at any time. Performance testing evaluated all modes and confirmed acceptable pressure accuracy, timer accuracy, inflation and deflation function, hose function, and fault and overpressure protection.

Accordingly, the differences in treatment modes and cycle characteristics do not adversely affect the safety or effectiveness of the subject device.

G. Performance characteristics

The Air Pressure Therapy System has been tested and met the requirements of the following standards:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 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+AMD1:2020 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
- IEC/TR 60601-4-2:2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO10993-5:2009 Biological evaluations of medical devices -- Part 5: Tests for In Vitro

cytotoxicity

- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests for Irritation
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications Part 2: Lithium systems
- Software Verification and Validation Testing
- The device also passed:
  - i. pressure accuracy and time accuracy testing
  - ii. seam strength testing to ensure cuffs do not burst if maximum pressure is exceeded
  - iii. failure mode verification and validation testing to ensure mitigation of overpressurization risk if there is a software failure.

H. Conclusion

Based on the above data, we can conclude that the proposed device is as safe, as effective as the predicate device. Thus, the subject device is substantially equivalent to the predicate device which cleared under K230500.