June 14, 2024

Xiamen Weiyou Intelligent Technology Co., Ltd.
℅ Libray Chang
Official Correspondent
Shanghai Spica Management Consulting Co., Ltd.
609 Room, No. 133 Shengang Avenue, Pudong New District
Shanghai, 201306
China

Re: K233238
Trade/Device Name: Air Pressure Therapy System (Model:VU-IPC4M)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 23, 2024
Received: May 23, 2024

Dear Libray Chang:

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.

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, Ph.D
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233238

Device Name
Air Pressure Therapy System (Model:VU-IPC4M)

Indications for Use *(Describe)*
Air Pressure Therapy System (Model:VU-IPC4M) 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.

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510(k) Summary
K233238

Type of Submission Traditional

Date Prepared June 11, 2024

Submission Sponsor

Manufacturer Name	Xiamen Weiyou Intelligent Technology Co., Ltd.
Address	Unit 3 No. 6 Xianghong Road, Torch Hi-Tech Zone Industrial Park, Xiang'an District, Xiamen P.R.China.
Tel	086-0592-6251545
Email	17916220@qq.com
Contact Person	Yong Sun

Device Identification

Trade Name	Air Pressure Therapy System (Model:VU-IPC4M)
Regulation Number	21 CFR 890.5650
Regulation Name	Powered inflatable tube massager
Device Classification	Class II
Product Code	IRP
Panel	Physical Medicine

Application Correspondent

Company Name	Shanghai Spica Management Consulting Co., Ltd.
Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China
Tel	86-13020102321
Email	Libray@spicagloble.com
Contact Person	Libray Chang

Indications for Use

Air Pressure Therapy System (Model:VU-IPC4M) 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

Air Pressure Therapy System (Model:VU-IPC4M) consists 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.

Predicate and Reference Device Information

Predicate (Primary):	THERAGUN, Inc.
Trade/Device Name	RecoveryAir PRO
510(K) number	K211745
Predicate (Secondary):	Wonjin Mulsan Co., Ltd.
Trade/Device Name	Compressible Limb and Circulation Therapy System
510(K) number	K211283
Predicate (Tertiary):	SLK Medical GmbH
Trade/Device Name	V12 PRO
510(K) number	K210913

Performance Testing - Clinical

Not Applicable.

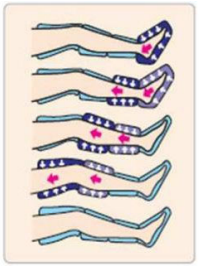
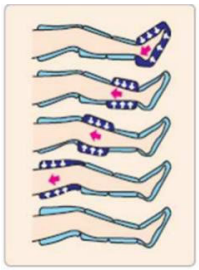
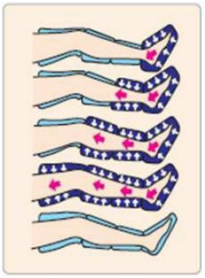
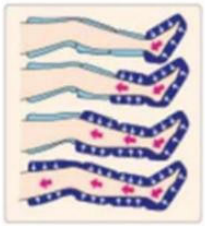
Performance Testing - Animal

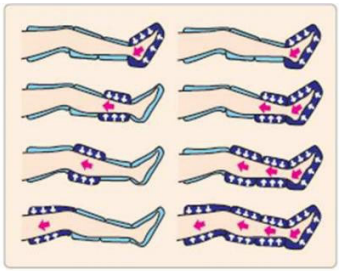
Not Applicable.

Table 6A: Summary of Comparison

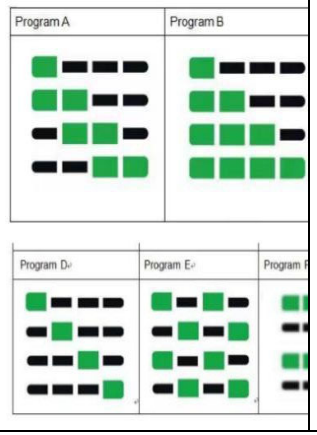
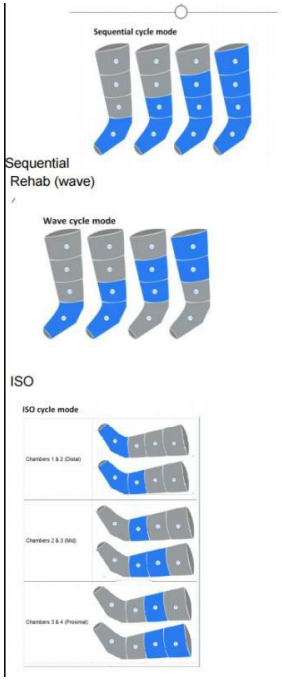
	Subject Device	Primary Predicate	Secondary Predicate	Tertiary Predicate	Differences Discussion
Device name	Air Pressure Therapy System (Model:VU-IPC4M)	RecoveryAir PRO (Model RecoveryAir PRO)	Compressible Limb and Circulation Therapy System	V12 PRO	N/A
510(k) number	K233238	K211745	K211283	K210913	N/A
Manufacturer	Xiamen Weiyou Intelligent Technology Co., Ltd.	Theragun Inc	Wonjin Mulsan Co., Ltd.	SLK Medical GmbH	N/A
Product regulation	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	Same
Classification name	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Same
Regulation class	2	2	2	2	Same
Product code	IRP	IRP	IRP	IRP	Same
Indications for use	Air Pressure Therapy System (Model:VU-IPC4M) is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase	The RecoveryAir PRO is an air compression therapy device intended to provide graduated pressure to compression garments. The RecoveryAir PRO is indicated for the temporary relief of minor muscle aches	POWER-Q2300 is intended for the temporary relief of minor muscle aches and pains, and for temporary increase in blood circulation to the treated areas in people who are in good health. POWER-Q2300 simulates	V12 PRO is a Compression Therapy System is intended for the temporary relief of minor muscle aches and pains and for the temporary	Same

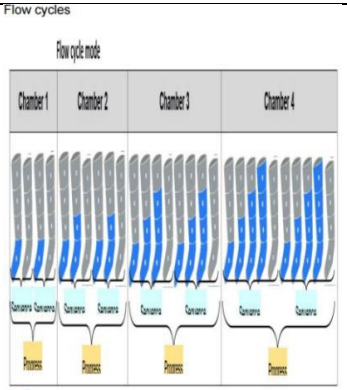
	circulation to the treated areas in people who are in good health.	and pains, and for temporary increase in blood circulation to the treated areas in people who are in good health. The RecoveryAir PRO simulates kneading and stroking of tissues by using an inflatable garment.	kneading and stroking of tissues by using an inflatable garment (cuff).	increase in circulation to the treated areas in people who are in good health. The V12 PRO Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	
Rx or OTC	OTC	OTC	OTC	OTC	Same
Power Source	11.1 V / 1600mAh Rechargeable Li-ion battery (100-240V AC input)	100-240V AC, 50/60 Hz, 12V or internal battery	110-120VAC, 50/60Hz	110-230V 50/60 Hz	Similar
Dimensions (W*H*L)	25.42*6.03*6.92CM	8.6in (L) *6.7in (W) *5.1in (H)	290 x 260 x 172 mm	6.69"x 7.87"x7.87"	Similar
Weight	0.58 kg	4.202 pounds	3.1 kg	4.4 pounds	Similar
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Same
Number of Chambers	4-chamber	4-chamber	4 Chambers	12 Chambers	Similar
Sleeve Materials	Nylon cloth +PUether amine	Polyether Nylon Fabric	/	Nylon with a Polyurethane laminate	Different
Modes	Mode A: In this mode,	Sequential, ISO or Rehab	Mode A:	Inflates chambers	Different,

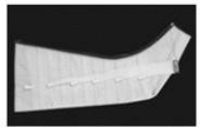
((Inflation sequences)	①chamber is inflated and the pressure is maintained after filling; ②chambers are inflated, chambers are inflated and ① chamber is deflated while maintaining pressure after filling; Similarly, the pressure is maintained after ③ chambers are filled, ④ chambers are inflated, and ② chambers are deflated; Then the cycle repeats. Mode B: In this mode, ①chamber is inflated and the pressure is maintained after filling; ②chamber inflation; the same as ③chamber and ④chamber; Then the cycle repeats. Mode C: In this mode,	(wave), 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 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 Wave mode: The first chamber inflates, and after a few seconds, the 1st and 2nd chamber starts to inflate until both chambers reach the set pressure. Then	 Mode B:  Mode C:  Mode D:	from bottom up but maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated. Sequential 	Although the subject device provides 7 kinds of work mode, the Mode A and Mode B are the same with Sequential, ISO or Rehab (wave) of Primary predicate device (K211745), while the other work modes of subject device just have difference about inflatable order of the different chambers. The treatment pressure range are the same under different work modes, so the difference of pressure range would not raise

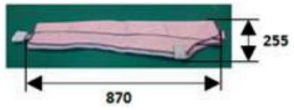
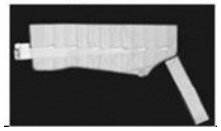
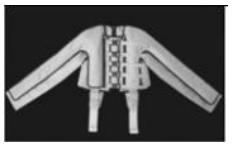
	the four chambers are inflated at the same time, the pressure is maintained after filling, and then the four chambers are deflated at the same time;After deflation, the four chambers are inflated at the same time;Then the cycle repeats. Mode D: In this mode, only a single chamber is inflated at a time. Starting from the chamber① and working up to the chamber④. Then the cycle repeats. Mode E: in this mode. ①③are inflated,then defalted, chamber ②④are inflated,then deflated;Then the cycle repeats.	the deflation on 1st chamber , the 2nd and 3rd chambers starts to inflate until the both chambers reach the set pressure; then deflate the 2nd chambers inflate 3rd and 4th chambers until the both chambers reach the set pressure Flow cycles Progress 1: first inflate Chamber 1 to target pressure, then hold & release. then go to Progress 2. Progress 2: first inflated Chamber 1 to target pressure, theninflate 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			adversely impact on safety and effectiveness.

	Mode F: in this mode. ①②are inflated,then defalted, chamber ③④are inflated,then deflated;Then the cycle repeats. ModeG: In this mode, chamber 1 inflates to set pressure, it pulses and holds pressure; Chamber 2 inflates to set pressure, pulses and holds pressure, chamber 1 is holding pressure at the same time; Chamber 3 inflates to set pressure, pulses and holds pressure, chamber 1 & 2 are holding pressure at the same time; While chamber 1 is deflating,chamber 4 inflates to set pressure, pulses and holds	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 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.			

	pressure, chamber 2 & 3 are holding pressure at the same time; In such way, it works up to chamber 4. Then the cycle repeats. remark: pulse means quick inflation and deflation for 4 times. 				

					
Anatomical site	Leg (including of foot, calf, knee, upper leg) Pants (including of upper leg, glutes, hips, lower back) Arm (including of entire arm, shoulder) Half-Leg (including of foot, calf, knee)	RecoveryAir Compression Boots: 95*28.7 cm	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower back) Arm (including of entire arm, shoulder) Half-Leg (including of foot, calf, knee)	Leg (consisting of foot, calf, knee, upper leg) Pant (consists of foot, calf, knee, upper leg, glutes, hips, lower back) Arm (consisting of entire arm, shoulder, upper chest and back) Jacket (consisting of entire arms, shoulder, upper chest and back)	Similar

Appearance and size of Cuffs	Leg:   Pants: 	/	Leg   Medium: 310x940mm Large: 390x990	Leg  32" x 30"  Pant 	Similar

	 Arm:  Waist: 		Hip   530x720mm Arm   Medium: 255x870mm Large: 330x895mm	Arm  22″ x 29″  Jacket 	

			Half-Leg   300x700mm		
Device Pressure range	30~180mmHg	20-100mmHg	20-200 mmHg	15-80 mmHg	Similar to K211283, Although the pressure value is different from that of the Primary Predicate and Tertiary Predicate, it is included in the pressure value range of the Secondary

					Predicate, so the pressure value of the Subject Device can be proven to not affect its safety and effectiveness
Treatment Time	Default 30min, APP Settings	10min-90min, step of 5min	User can select operation time from 15 and 30 minutes.	User determines therapy time.Choose from 15 to 60 minutessession time.	Different, Although the treatment time range of subject device is set by APP, but the default value is 30min which is included in the range of the comparison equipment. In the process of use, the user can start or stop the button on the hand controller at any time, so the difference of Treatment time

					would not raise adversely impact on safety and effectiveness.
Hold time within cycle	30-180 sec	2-10 sec.	1 min 20 sec	1 min 15 sec	Similar
Pause interval - between cycles	15 sec	10 - 70 sec	Adjustable at interval of 0/5/10/30 sec at modes A and B Fixed at 30 sec at modes C and D	/	Similar
Mobile application	Bluetooth communication	Bluetooth communication	/	/	Same
Patient contact	Non-conductive appliances	Non-conductive appliances	/	/	Same
Software/Firmware/Microprocessor Control	Microprocessor	Microprocessor	/	Firmware/Microprocessor	Similar
Technology	Compressor and valve system which sequentially inflates inflatable chambers	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 sequentially	Same
Electrical safety EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1:2005; IEC 60601-1-2:2014; IEC60601-1-11:2015	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993	Same

Performance Characteristic

The device meets all the applicable technical requirements of :
IEC 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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
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
ISO 10993-10: 2010 - Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-5:2009 - Biological Evaluation of Medical Device - Part 5: Tests for in vitro Cytotoxicity
IEEE ANSI USEMCSC C63.27-2021-American National Standard for Evaluation of Wireless Coexistence
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

Conclusion

Based on the indications for use, technological characteristics, and non-clinical performance data, “Air Pressure Therapy System (Model:VU-IPC4M) ” 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.