June 22, 2021

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

Re: K201935
Trade/Device Name: Air Pressure Therapy System: VU-IPC04B
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: February 3, 2021
Received: June 2, 2021

Dear Sam Lin:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201935

Device Name
Air Pressure Therapy System: VU-IPC04B

Indications for Use *(Describe)*
Air Pressure Therapy System VU-IPC04B is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

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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K201935: 510(k) Summary

Type of submission Traditional

Date prepared February 3, 2021

Submission sponsor

Manufacturer name	Xiamen Weiyou Intelligent Technology Co., Ltd.
Address	Unit 101-401, No.6 Xianghong Road, Xiang'an District, Xiamen, Fujian, China
Tel	86-0592-6251545
Email	17916220@qq.com
Contact person	Yong Sun

Device identification

Classification name	Massager, Powered Inflatable Tube
Trade name	Air Pressure Therapy System: VU-IPC04B
Device classification	Class II
Regulation number	21 CFR 890.5650
Panel	Physical Medicine
Product code	IRP
Previous submissions	**None**

Application correspondent

Company name	Shanghai Spica Management Consulting Co., Ltd.
Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China
Tel	86-15626132181
Email	sam@spicagloble.com
Contact person	Sam Lin

Predicate and reference device information

Sponsor	NORMATEC INDUSTRIES, LP X
Trade/Device name	NormaTec Pulse and NormaTec Pulse Pro
510K number	K160608
Regulation number	21 CFR 890.5650

Indications for use of the device

Air Pressure Therapy System VU-IPC04B is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

Device description

Air Pressure Therapy System has a pump. The pump is connected to the dedicated cuff via the hose series, one cuff has 6 compression chambers. The pump compresses and inflates air into the chambers continuously to produce compression from the body tail end to body center and release the air after compression as one cycle process. Cycle time and pressure can be adjusted by purpose to avoid any discomfort.
Air Pressure Therapy System intermittent pneumatic compression could be used in family for improving blood circulation in the treated area, in exercise rehabilitation field for muscle relaxation before exercise and muscle rehabilitation after exercise to relieve muscle soreness.

Performance testing - clinical

Not Applicable.

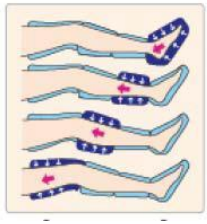
Performance testing - animal

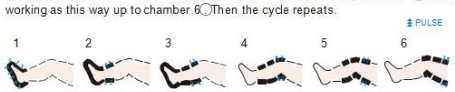
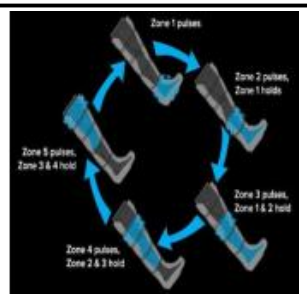
Not Applicable.

Table 6A: Summary of Comparison

	Subject device	Predicate device	Differences discussion
Device name	Air Pressure Therapy System: VU-IPC04B	NormaTec Pulse and NormaTec Pulse Pro	
510(k) number	K201935	K160608	N/A
Manufacturer	Xiamen Weiyou Intelligent Technology Co., Ltd.	NORMATEC INDUSTRIES, LP X	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	Air Pressure Therapy System VU-IPC04B is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	Same
Rx or OTC	OTC	OTC	Same
Pressure range	30-110mmHg	30-110mmHg	Same
Treatment time	5-99mins	Stays on until the user turns it off or can be set up to turn off in a range of 10 mins to continuous / User controlled 10 minutes to 175 minutes or continuous –total time over 4	Similar The treatment time of subject device is smaller than predicate device (K160608), so the difference of treatment

		segments.	time would not raise adversely impact on safety and effectiveness.
Standard	IEC 60601-1-11, ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, IEC 60601-1-2, ISO 10993-10, ISO 10993-5, IEC 62133-2	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Similar
Mode of compression	Sequential	Sequential	Same
Power source	110-240V; 50Hz/60Hz	100- 240 VAC input	Similar
Power consumption	35W	14W	Similar
Dimensions(W*H*D)	22*14*9CM	4” x 5” x 9”	Similar
Weight	1.6KG	3.6 pounds	Similar
Photo		N/A	Similar
Size and appearance of sleeves (leg part)	 M: 91x65cm XL: 110x70cm(overlapping) XXL: 125x76cm(overlapping)	Short: 14” x 43” Standard: 14” x 48” Tall: 14” x 60”	Similar
Housing materials	Molded ABS enclosure	Molded ABS enclosure	Same
Number of chambers	6 chambers	5 chambers	Similar

Work mode	Mode A: In this mode, only a single chamber is inflated at a time. Starting from the chamber ① and working up to the chamber ⑥. Then the cycle repeats. Mode B: In this mode, the chamber ① stays inflated. It gradually adds a chamber until all six chambers are filled with air. Then the cycle repeats. Mode C: In this mode, chamber ① inflates & deflates 4 times, then holds pressure; next chamber ② inflates & deflates 4 times, chamber ①② hold pressure; chamber ③ inflates & deflates 4 times, chamber ②③ hold pressure, chamber ① deflates; chamber ④ inflates & deflates 4 times, chamber ③④ hold pressure, chamber ② deflates; working as this way up to chamber ⑥. Then the cycle repeats. Note: Under this mode, for the FIRST CYCLE, it works as mode B to warm up; from the 2nd cycle on, it works as PULSE Mode C. Mode D: In this mode, all chambers inflates together, and deflates together. Then the cycle repeats.	Sequential mode: Starting with the distal chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the top section decompresses, the cycle begins again. again.  Normatec Pulse mode: Starting with the distal zone and progressing up the proximal zone, one zone compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air of previous two zone, the other zones do not hold, until the last zone finished, deflate the all last three zone then enter into next cycle.	Although the subject device provides 4 kinds of work mode, the Mode A and Mode C are the same with predicate device (K160608), 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 adversely impact on safety and effectiveness.

	A: In this mode, only a single chamber is inflated at a time. Starting from the chamber ① and working up to the chamber ⑥ Then the cycle repeats.  **B:** In this mode, the chamber 1 stays inflated. It gradually adds a chamber until all six chambers are filled with air. Then the cycle repeats.  **C:** In this mode, chamber 1 inflates & deflates 4 times, then holds pressure; next chamber 2 inflates & deflates 4 times, chamber 1 2 hold pressure; chamber 3 inflates & deflates 4 times, chamber 2 3 hold pressure, chamber 1 deflates; chamber 4 inflates & deflates 4 times, chamber 3 4 hold pressure, chamber ② deflates; working as this way up to chamber 6 Then the cycle repeats.  Note: Under this mode, for the FIRST CYCLE, it works as mode B to warm up; from the 2nd cycle on, it works as PULSE mode C. **D:** In this mode, all chambers inflates together, and deflates together. Then the cycle repeats. 		
Safety feature	Power button on main unit allows user to stop therapy session at any time	Power button on main unit allows user to stop 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

Performance Characteristic

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
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
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

Conclusion

Based on the indications for use, technological characteristics, and non-clinical performance data, “Air Pressure Therapy System: VU-IPC04B (K201935)” is as safe, as effective, and performs as well as the legally marketed predicate devices, “NormaTec Pulse and NormaTec Pulse Pro (K160608)”. Therefore, the subject device is substantially equivalent to the predicate device.