April 30, 2026

Xiamen WeiYou Intelligent Technology Co.,Ltd.
% Ariel Xiang
Primary Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.,
Shanghai, Shanghai 200122
China

Re: K253064
Trade/Device Name: Air Pressure Therapy System (VU-IPC8M); Air Pressure Therapy System (VU-IPC6M); Air Pressure Therapy System (VU-IPC4X)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: March 29, 2026
Received: March 30, 2026

Dear Ariel Xiang:

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.	K253064

Please provide the device trade name(s).

Air Pressure Therapy System (VU-IPC8M);
Air Pressure Therapy System (VU-IPC6M);
Air Pressure Therapy System (VU-IPC4X)

Please provide your Indications for Use below.

Air Pressure Therapy System is intended 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 (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510K Summary

Prepared:2025/04/30

A. Applicant

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Address：Unit 101-401, No.6 Xianghong Road, Xiang'an District, Xiamen,Fujian, China

Contact Person:Kelly Guo

Tel:+86-0592-6251545

mail:sales@weiuit.com

B. Proposed Device

Device Name: Air Pressure Therapy System

Model(s):VU-IPC8M,VU-IPC6M,VU-IPC4X

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 Pressure Therapy System VU-IPC04B

Regulation Number: 21 CFR 890.5650

Regulation Name: Powered inflatable tube massager

Regulatory Class: Class II

Product Code: IRP

510(k) Number: K243320

D． Device Description[i]

Air Pressure Therapy System: A powered inflatable massage device designed to simulate kneading and stroking of tissue by use of an inflatable garment, providing temporary relief for minor muscle discomfort and to temporarily increase local circulation.

The system includes a control unit, a selection of multi-chamber pants cuffs (4, 6, 8 chambers) for legs and hips. Each chamber incorporates a separate pump unit to enable individual control of each chamber.

Cuffs are crafted from Nylon cloth and thermoplastic polyurethane (TPU), offered in black

The Air Pressure Therapy System is charged using an external compliant power supply as well as powered by an internal IEC 62133-2 compliant lithium-ion battery.

In addition, the devices have Bluetooth capability that allows the use of a Mobile app to control the device. The Bluetooth app allows the user to use a compatible Android or iOS phone to select and set device parameters, such as, set time, select treatment mode.

E . Indication for use

Air Pressure Therapy System is intended 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.

F. Technological Comparison

Item	**Proposed device**	**Predicate device**	**Discussion**
Device name	Air Pressure Therapy System	Air Pressure Therapy System	-
Model	VU-IPC8M,VU-IPC6M,VU-IPC4X	VU-IPC04B	-
510(k) number	K253064	K243320	-
Manufacturer	Xiamen Weiyou Intelligent Technology Co., Ltd.	Xiamen Weiyou Intelligent Technology 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 Pressure Therapy System is intended 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.	Air Pressure Therapy System is intended 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.	Identical
Rx or OTC	OTC	OTC	Identical
Intended user	Adult	Adult	Identical

<table>
<tr><td>Environment of use</td><td>Clinics, hospital, athlete, training, and home environments.</td><td>Clinics, hospital, athlete, training, and home environments.</td><td>Identical</td></tr>
<tr><td>Mode of compression</td><td>Sequential</td><td>Sequential</td><td>Identical</td></tr>
<tr><td>Power source</td><td>AC100-240V; 50Hz/60Hz</td><td>10.8 V / 5000mAh Rechargeable Li-ion battery

(100-240V AC input 50Hz/60Hz)</td><td>Similar, NOTE1</td></tr>
<tr><td>Power consumption</td><td>45VA</td><td>35VA</td><td>Similar, NOTE1</td></tr>
<tr><td>Software /

Firmware

Micro-processor

Control</td><td>Microprocessor</td><td>Microprocessor</td><td>Identical</td></tr>
<tr><td>Technology</td><td>Compressor and valve system which sequentially inflates inflatable chambers.

Bluetooth communication ability.</td><td>Compressor and valve system which sequentially inflates inflatable chambers.</td><td>Identical</td></tr>
<tr><td>Safety feature</td><td>Button on display allows user to stop or pause therapy session at any time</td><td>Power button on main unit allows user to stop therapy session at any time.</td><td>Identical</td></tr>
<tr><td>Pressure range</td><td>30-180mmHg（±20mmHg）</td><td>30-240 mmHg</td><td>Identical</td></tr>
<tr><td>Pressure levels</td><td>16 levels

<table>
<tr><td>Level</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td></tr>
<tr><td>mmHg</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td><td>100</td></tr>
<tr><td>Level</td><td>9</td><td>10</td><td>11</td><td>12</td><td>13</td><td>14</td><td>15</td><td>16</td></tr>
<tr><td>mmHg</td><td>110</td><td>120</td><td>130</td><td>140</td><td>150</td><td>160</td><td>170</td><td>180</td></tr>
</table></td><td>16 levels

<table>
<tr><td>Pressure level</td><td>Level 1</td><td>Level 2</td><td>Level 3</td><td>Level 4</td><td>Level 5</td><td>Level 6</td><td>Level 7</td></tr>
<tr><td>Pressure (mmHg)</td><td>30</td><td>44</td><td>58</td><td>72</td><td>86</td><td>100</td><td>114</td></tr>
<tr><td>Pressure level</td><td>Level 9</td><td>Level 10</td><td>Level 11</td><td>Level 12</td><td>Level 13</td><td>Level 14</td><td>Level 15</td></tr>
<tr><td>Pressure (mmHg)</td><td>142</td><td>156</td><td>170</td><td>184</td><td>198</td><td>212</td><td>226</td></tr>
</table></td><td>similar</td></tr>
<tr><td>Treatment time</td><td>Default 30 minutes,5-99mins(optional)</td><td>Default 30 minutes,5-99mins(optional)</td><td>Identical</td></tr>
<tr><td>Inflation time</td><td>Reaching level 1 takes 108 seconds. increasing by 8 seconds per level.

Stop inflating when the setting pressure level is reached.</td><td>Model A&B&C:70 seconds

Model D:140 seconds

Stop inflating when the design pressure is reached.</td><td>Identical</td></tr>
</table>

<table>
<tr><td>Pressure Holding Time</td><td colspan="3">Default 2 seconds.0-5 seconds (optional)</td><td>Model A&C&D:0 seconds
Model B:3 seconds</td><td>Similar</td></tr>
<tr><td>Deflation time</td><td colspan="3">Default 20 seconds,0-50 seconds (optional)</td><td>Model A&C:2 seconds, Model B:22 seconds, mode D:30 seconds</td><td>Similar</td></tr>
<tr><td>Cycle time</td><td colspan="3">Default 20 seconds,0-50 seconds (optional)</td><td>Specific data has not been disclosed.</td><td>Similar, NOTE1</td></tr>
<tr><td>Material of Patient contact components</td><td colspan="3">Nylon</td><td>Nylon</td><td>Identical</td></tr>
<tr><td>Product Weight</td><td colspan="3"><table><tr><td>VU-IPC8M</td><td>VU-IPC6M</td><td>VU-IPC4X</td></tr><tr><td>5kg</td><td>4.2kg</td><td>3.7kg</td></tr></table></td><td>1.5kg</td><td>Similar, NOTE1</td></tr>
<tr><td>Main unit dimensions (length*width*height)</td><td colspan="3">10 ×7.8 × 4.6CM</td><td>30*23.7*12.6CM</td><td>Similar, NOTE1</td></tr>
<tr><td>Housing materials</td><td colspan="3">Molded ABS enclosure</td><td>Molded ABS enclosure</td><td>Identical</td></tr>
<tr><td>User Interface and function</td><td colspan="3">  </td><td>  </td><td>Similar, NOTE 1</td></tr>
<tr><td>Product model</td><td>VU-IPC8M</td><td>VU-IPC6M</td><td>VU-IPC4X</td><td>VU-IPC04B</td><td>/</td></tr>
<tr><td>Cuff model</td><td>Go X Pants</td><td>Go X Lite Pants</td><td>Go XMini Pants</td><td>/</td><td>/</td></tr>
<tr><td>Number of chambers/the number of chambers that can be pressurized simultaneously</td><td>8 chambers*2</td><td>6chambers *2</td><td>4 chambers *2</td><td>6 chambers*2</td><td>Similar, NOTE 1</td></tr>
<tr><td>Dimensions and Appearance</td><td colspan="3">Pants cuff,
M:142*80CM, ±5%
L:148*72CM, ±5%</td><td>Pants cuff, 142*83cm</td><td>Similar, NOTE 1</td></tr>
</table>

Connection method between the host and cuff	Control unit connected to inflatable cuff via a hose.	Control unit connected to inflatable cuff via a hose	Identical
Work mode/ Treatment Mode	Eight modes(ABCDEFGH)	Four modes(ABCD)	Similar
user controls	Main unit/Remote operation via Bluetooth app	Main unit	Similar
software	Enterprise self-developed algorithms, VU-IPC8M:Version 3.8 VU-IPC6M:Version 1.8 VU-IPC4X:Version 1.5	Enterprise self-developed algorithms, Version 1.0	Similar, NOTE 2
Bluetooth	YES, FCC ID: 2BOPZ-BLE020 Bluetooth specifications: Low-power Bluetooth 4.2 Operation Frequency: 2402 to 2480 MHz Modulations: GFSK Transmit Power: 0 dBm Receiver Sensitivity: -90 dBm Security: AES HW Transmission Range: ≤10 meters	NO	NOTE 2
mobile app	YES, iOS and Android	NO	NOTE 2
cloud storage of data	Amazon Cognito	NO	NOTE 2

NOTE 1:

Although the device design appearance and specification parameter between the predicate devices and proposed device are different, they are both complied with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. So, the minor differences in such parameters (power source, Control Unit, Size of cuffs, Number of chambers and weight, Cycle time) do not affect the safety and effectiveness.

NOTE 2:

Although the software version of the proposed device has been upgraded compared to the predicate device and can be controlled via a Bluetooth-connected app, the proposed device has passed software verification and testing according to IEC 62304 and complies with FCC 47 CFR 15.247 and RF exposure requirements, ANSI C63.27 wireless coexistence. Concurrently, cybersecurity testing and evaluation were conducted in accordance with the FDA guidance document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issued on June 27, 2025”.

The results demonstrated that the device is safe and reliable. So, the difference between the subject device and predicated device will not raise any new concerns regarding the safety and effectiveness.

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