June 10, 2026

Xiamen Weiyou Intelligent Technology Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg.
#1500 Century Ave.
Shanghai, 200122
China

Re: K253919
Trade/Device Name: Cryo And Thermo Therapy System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: May 12, 2026
Received: May 13, 2026

Dear Eva Li:

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.	K253919

Please provide the device trade name(s).

Cryo And Thermo Therapy System (VU-COT01-V1; VU-COT01-V2; VU-COT02; VU-COT03)
Cuff Models: Arm Cuff (CC-EA); Waist Cuff (CC-WA); Knee Cuff (CC-KA); Shoulder Cuff (CC-SA); Foot/ Calf Cuff (CC-FA); Ankle Cuff (CC-AA); Leg Cuff (CC-LA); Knee Cuff (CC-K); Arm Cuff (CC-E).

Please provide your Indications for Use below.

Cryo And Thermo Therapy System (Model:VU-COT02) :
The device provides a combination of cold, heat, contrast, and compression therapies.
It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated.
It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated.
The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings and home settings.

Cryo And Thermo Therapy System (Model: VU-COT01-V1, VU-COT01-V2, VU-COT03) :
The device provides a combination of cold, heat, contrast, and compression therapies.
It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated.
It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated.
The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

(K253919)

1. General Information

Applicant name	Xiamen Weiyou Intelligent Technology Co., Ltd.
Address	Unit 301 No. 6 Xianghong Road, Torch Hi-Tech Zone Industrial Park, Xiang'an District, Xiamen, P.R.China
Contact	Kelly Guo

Date prepared： June 08, 2026

Device name
Device Trade Name: Cryo And Thermo Therapy System
Common Name: Powered inflatable tube massager
Classification name: Massager, Powered Inflatable Tube
Regulation Number: 890.5650
Product Code: IRP, ILO

Legally Marketed Predicate Deice
K242754
Z-ONE, ZT Cube (ZC3), ZT Clinic
ZAMAR Medical d.o.o.

2. Device Description
AC-powered, software-controlled multi-modality devices, designed to impart localized heat exchange and compression therapies. The devices have been developed with the possibility of choosing between different programs: cold therapy and heat therapy. Moreover, they also possess an intermittent pneumatic compression activity, which is the effect of an alternating compression and decompression.

The Cryo And Thermo Therapy System have 4 models :
VU-COT01-V1;
VU-COT01-V2;
VU-COT02;
VU-COT03

And the Cuff has different option models:
Arm Cuff (CC-EA);
Waist Cuff (CC-WA);
Knee Cuff (CC-KA);
Shoulder Cuff (CC-SA);
Foot/Calf Cuff (CC-FA)·
Ankle Cuff (CC-AA);

Leq Cuff (CC-LA);
Knee Cuff (CC-K);
Arm Cuff (CC-E).

2.1 VU-COT01-V1/VU-COT01-V2

These models are designed to deliver both cooling and heating therapy. The temperature range for heat is 38℃-40℃, while that for cold is 3℃-15℃. The treatment pressure range is from 30 to 120 mmHg.

It is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

2.2 VU-COT02

This model is designed to circulate water only. The device cannot provide cooling or heating. The water temperature is determined by the temperature of the water that the user adds to the reservoir.

It is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings, and home setting.

2.3 VU-COT03

This model is designed to deliver both cooling and heating therapy. The temperature for heat is one option 40℃, while that for cold is range from 5℃ to 15℃.

It is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

3. Indication for use

Cryo And Thermo Therapy System (Model:VU-COT02) :
The device provides a combination of cold, heat, contrast, and compression therapies. It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated.
It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated. The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings and home settings.

Cryo And Thermo Therapy System (Model: VU-COT01-V1, VU-COT01-V2, VU-COT03) :
The device provides a combination of cold, heat, contrast, and compression therapies. It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated.

It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated. The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

4. Substantial equivalence comparison

In the table below a detailed comparison of the subject devices Cryo And Thermo Therapy System (VU-COT01-V1, VU-COT01-V2, VU-COT02, VU-COT03) and predicate device Z-ONE, ZT Cube, ZT Clinic

Comparison table

Characteristic	Predicate device(K242754)	Subject device(K253919)	Comparison
	Z-ONE, ZT Cube, ZT Clinic	Cryo And Thermo Therapy System	
Manufacturer	ZAMAR Medical D.o.o	Xiamen Weiyou Intelligent Technology Co., Ltd.	
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	same
Classification Product Code	IRP	IRP	Same
Subsequent Product Code	ILO	ILO	same
Indications for use	The Heat Exchange Equipment for Cryotherapy and Thermotherapy provides a combination of cold, heat, contrast, and compression therapies. It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated. The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings	VU-COT01-V1, VU-COT01-V2, VU-COT03: The device provides a combination of cold, heat, contrast, and compression therapies. It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated. The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings VU-COT02: The device provides a combination of cold, heat, contrast, and compression therapies. It is intended to treat post-surgical and trauma injuries to reduce edema, swelling and pain, for which cold and compression are	Different*1

		indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions, for which localized thermal therapy (hot or cold or contrast) are indicated. The equipment is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home setting	
Intended Users	Health Care Professionals only (Prescription use)	Health Care Professionals only (Prescription use)	same
Where used (hospital, home, ambulance, etc)	Intended for indoor use only such as rehabilitation clinics, outpatient clinic, athletic training settings.	VU-COT01-V1, VU-COT01-V2, VU-COT03: Intended for indoor use only such as rehabilitation clinics, outpatient clinic, athletic training settings VU-COT02: Intended for indoor use only such as rehabilitation clinics, outpatient clinic, athletic training settings, and home setting.	Different *1
Number of Patients that can be treated	Two patients with single locations or two anatomical locations on one patient. 4 possible connections with ZT Clinic	2 options: Two patients with single locations or two anatomical locations on one patient. 1 patient	similar
Physical unit			
Energy used and/or delivered	AC powered	AC powered	same
User Interface	Display touchscreen Z-ONE: 5'' ZT Cube: 7'' ZT Clinic: 10,4''	VU-COT01-V1, VU-COT02: 5''Segment screen VU-COT01-V2: 5'' touch scree VU-COT03: 4.3''touch scree	similar
Design	Z-ONE: portable unit, equipped with a handle for moving. ZT Cube: portable unit, equipped with a handle for moving.	VU-COT01-V1/ VU-COT01-V2: portable unit, equipped with a handle and Back strap for moving	similar

	ZT Clinic: wheeled model, with brakes.	VU-COT02/ VU-COT03: portable unit, equipped with a handle for moving	
Dimensions	Z-ONE: 11” x 10” x 12”H ZT Cube: 15” x 12” x 13”H ZT Clinic: 15” x 22” x 37”H	VU-COT01-V1/ VU-COT01-V2:20” x 11” x 11”H VU-COT02:13” x 8” x 10”H VU-COT03:11” x 7” x 13”H	similar
Weight empty	Z-ONE: 20 lbs (9kg) ZT Cube: 31 lbs (14kg) ZT Clinic: 95 lbs (43kg)	VU-COT01-V1/ VU-COT01-V2:22 lbs（10kg） VU-COT02:5.8 lbs（2.6 kg） VU-COT03: 11.6lbs（5.3kg）	similar
Weight fully loaded	Z-ONE: 26 lbs (12kg) ZT Cube: 37 lbs (17kg) ZT Clinic: 106 lbs (48kg)	VU-COT01-V1/VU-COT01-V2: 44lbs（20kg） VU-COT02: 22lbs（10 kg） VU-COT03:28.6 lbs（13kg）	similar
Chilling Mechanism	Combination of a refrigeration system with a hydraulic system	VU-COT01-V1/VU-COT01-V2/ VU-COT03: Combination of a refrigeration system with a hydraulic system VU-COT02: External cold water circulation	similar
Heating Mechanism	Combination of a refrigeration system (with the aid of 4-way valve to force the reverse cycle) with a hydraulic system.	VU-COT01-V1/VU-COT01-V2/ VU-COT03: Combination of a refrigeration system with a hydraulic system VU-COT02: External hot water circulation	similar
Reservoir Fluid Capacity	Single reservoir of about one liter	VU-COT01-V1,VU-COT01-V2： hot water tank 1.7L and cold water tank 0.7L VU-COT02: single water tank1.7L VU-COT03: single water tank4.5L	similar
Functions			
Heat Therapy	Available within the specific temperature ranges of the models, either without compression or with low compression.	VU-COT01-V1,VU-COT01-V2, VU-COT03:Available within the specific temperature ranges of the models, either without compression or with low compression.	similar

	Z-ONE: only cold therapy	VU-COT02: The device cannot be heated and it depends on the external water temperature.	
Heat Therapy Treatment time	5 to 30 minutes.	5 to 99miutes adjustable Default: 30 minutes	similar
Cold Therapy	Available without and with compression in 4 levels (Low, Medium-low, Medium, High)	Available without and with compression	similar
Cold Therapy Treatment Time	5 to 90 minutes.	VU-COT01-V1, VU-COT02: 5 to 99 minutes. VU-COT01-V2, VU-COT03: 5 to 90 minutes.	similar
Contrast Therapy	Available for ZT Cube and ZT Clinic. Treatment cycles of Cryotherapy, Thermotherapy, Pause and Repeat can be individually set. Treatment up to 90 minutes. Not available for Z-ONE.	Available for VU-COT01-V1, VU-COT01-V2. Not available for VU-COT02, VU-COT03.	similar
Compression range	Available in four levels Low: 15 mmHg Medium-low: 40 mmHg Medium: 60 mmHg High: 80 mmHg Possibility of selecting compression time applied to the treated part, intermittent compression.	VU-COT01-V1,VU-COT01-V2,VU-COT02:10 level adjustable ranging 30-120mmHg VU-COT03: low-40mmHg, medium-70mmHg, high-100mmHg	similar
Temperature range	Z-ONE: 41°F - 59°F ZT Cube: 34°F - 104°F ZT Clinic: 34°F – 113°F	**Cold:** VU-COT01-V1,VU-COT01-V2:37°F-59°F VU-COT03: 41°F - 59°F **Heat:** VU-COT01-V1, VU-COT01-V2:100°F-104°F VU-COT03:104°F	similar
Software features	Electronic pressure control and therapy time and temperature monitoring.	Electronic pressure control and therapy time and temperature monitoring.	same
Electrical characteristic			
Line Voltage	115V	100-240V	similar
Line Frequency	60 Hz	50/60Hz	similar

Electrical Safety Standards	• IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION • ANSI AAMI ES60601 1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] • IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Type BF	VU-COT01-V1,VU-COT01-V2,VU-COT03: • IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION • ANSI AAMI ES60601 1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] • IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Type BF VU-COT02: • IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION • ANSI AAMI ES60601 1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] • IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Type BF • IEC 60601-1-11:2020	Similar
Environmental characteristics			
Operating Temperature	50°F - 86°F (10°C – 30°C)	10℃~40℃	similar
Storage Temperature	50°F - 104°F (10°C – 40°C)	-40℃~70℃	similar
Operating Humidity	Relative humidity 10% - 50%	Relative humidity 30%-85%RH	similar
Storage Humidity	Relative humidity 30%-60%	Relative humidity 10%-100%RH	similar
Operating Atmospheric Pressure	0 – 6,500 Ft (0 – 2,000 m)	50kPa-106kPa	similar
Expected lifetime	5 years	5 years	same

Cuff			
Types of cuff	The cuffs are available for different parts of the body: full leg, shoulder, thigh, knee calf, lumbar, elbow wrist, ankle, knee, hip.	The cuffs are available for different parts of the body: arm cuff-all in one, waist cuff-all in one, knee cuff-all in one, shoulder cuff-all in one, foot+calf cuff-all in one, ankle cuff-all in one, leg, arm, knee	similar
Cuff technology	Flexible cuffs, formed by two separated chambers: one for the compression activity and one with a coil allowing the passage of the NON TOX liquid.	Flexible cuffs, The cuff is formed by pressing three layers of fabric into two chambers. One chamber is used for applying pressure, and the other for cold or hot water compresses.	similar
Patient Contacting Material	Polyether Polyurethane	Nylon	Different*2
Expected lifetime of accessories	1 years or 200 applications	6 months	Different*2
Sterility	Provided non-sterile only	Provided non-sterile only	same

Discussion:

Different*1, Model VU-COT02 pass the testing of IEC 60601-1-11, so home setting is safety and effective for this model.

Different*2, The material and expected lifetime of the wraps are different. These differences are mitigated by limiting skin contact with the wraps and with labeling addressing appropriate integrity conditions of wraps. Therefore, these differences do not raise questions of safety or effectiveness.

5. **Non- Clinical testing**

Performance of the subject device have been evaluated and tested by performing
- Temperature accuracy
- Pressure accuracy
- Pressure leak performance
-Pressure resistance of cuff (seam strength)

Results of the tests indicated that the devices conform to theirs predetermined specifications and operate within safety limits.

The durability of the thermal wraps has been tested under simulated real-use conditions, demonstrating the device's ability to maintain its integrity and performance over 6 month (Equal to 182.5 hours) repeated application cycles and maintain safety limits.

The device also pass the following testing:

(a) ANSI AAMI ES60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1)".

(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".

And the device(VU-COT02) passed IEC 60601-1-11 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

6. **Clinical testing**

N/A

7. Conclusion.

In conclusion, the testing data validates that the subject devices perform as intended under their proposed use conditions. The Cryo And Thermo Therapy System meets all safety and performance requirements, confirming substantial equivalence to the predicate device (K242754) in terms of indications for use and technological characteristics.