July 23, 2025

Xiamen Taotao Technology Co.,Ltd.
℅ Kiwi Xu
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K242615
Trade/Device Name: Intermittent pressure compression system (Compression Pump PT1005A; Leg Compression Cuffs; L-1001S, L-1001L, L-1001XL, L-1001XXL, L-1001XXXL)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 25, 2025
Received: June 25, 2025

Dear Kiwi Xu:

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.

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

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)*

K242615

Device Name

Intermittent pressure compression system (Compression pump, PT1005A; Leg compression cuffs, L-1001S, L-1001L, L-1001XL, L-1001XXL, L-1001XXXL)

Indications for Use *(Describe)*

The device 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.

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.

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510(k) Summary

Intermittent Pressure Compression System
K242615

Document prepared date: 2025/07/23

A. Applicant:

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B. Subject device:

Trade name: Intermittent Pressure Compression System (Compression Pump, PT1005A; Compression Leg Cuffs, L-1001S, L-1001L, L-1001XL, L-1001XXL, L-1001XXXL)

Common name: Powered inflatable Tube Massager

Classification name: Massager, Powered Inflatable Tube

Regulation Medical Specialty : Physical Medicine

Regulation Number	890.5650
Product Code	IRP
Classification	Class II

C. Predicate device:

K243320
Air Pressure Therapy System (VU-IPC04B)
Xiamen Weiyou Intelligent Technology Co., Ltd.

D. Indications for Use:

The device 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.

E. Device Description:

Air Pressure Therapy System is a powered inflatable tube massager. The device simulates manual kneading and stroking of tissues by sequential inflated cuffs, to temporarily relieve minor muscle aches and/or pains and to temporarily increase circulation to the treated areas.It consists of a main unit, a 4-chamber leg cuff, and an air hose for connecting the unit to the cuff. Only one leg is treated during the treatment process. The cuff inflates and deflates sequentially to apply the pressure on the leg which is controlled by the main unit.Each cuff is equipped with a dedicated air hose. It is to be used by adults.

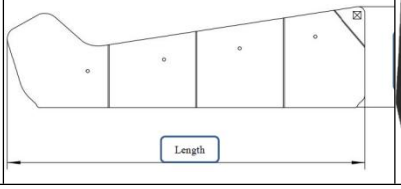
F. Technical Characteristic:

Product Name & model	Intermittent Pressure Compression System (Compression Pump, PT1005A; Compression Leg Cuffs, L-1001S, L-1001L, L-1001XL, L-1001XXL, L-1001XXXL)
Pressure (mmHg)	20~200 mmHg
Mode	1-6 model
Cycle time	30s
Pressure Time	Time 0-30 min, selection (10, 20, 30min)

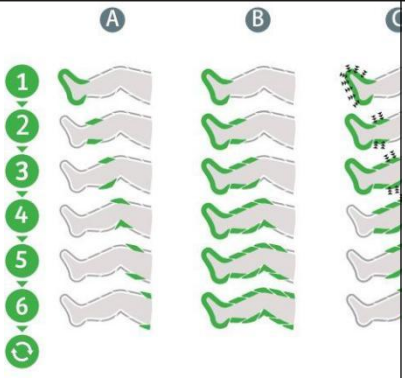
G. Substantial Equivalence Table:

Device	Subject Device (-)	Predicate device（K243320）	SE discussion
Device Name	Intermittent pressure compression system	Air Pressure Therapy System	--
510(k) ID	K242615	K243320	
Manufacturer	Xiamen Taotao Technology Co.,Ltd.	Xiamen Weiyou Intelligent Technology Co., Ltd.	
Model Name	Compression Pump, PT1005A; Compression Leg Cuffs, L-1001S, L-1001L, L-1001XL, L-1001XXL, L-1001XXXL	VU-IPC04B	--
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Same
Indications for Use	The device is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas	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 in people who are in good health.	Same

Device	Subject Device (-)	Predicate device（K243320）	SE discussion
	in people who are in good health.		
Rx or OTC	OTC	OTC	Same
Environment of use	Clinics, hospital, athlet,training, and home environments.	Clinics, hospital, athlet,training, and home environments.	Same
Medical Indications	Relieve muscle pain, relax muscles, increase blood circulation	Relieve muscle pain, relax muscles, increase blood circulation	Same
Mode of Compression	Sequential	Sequential	Same
Power Source	100-240Vac 50/60Hz	10.8 V / 5000mAh Rechargeable Li-ion battery (100-240V AC input 50Hz/60Hz)	Different The voltage and current of the power supply are the same. The difference in battery specifications will not affect safety.
Therapy Time	0 – 30 mins	5-99mins	Different Shorter treatment time enhances the safety of use.
Max Pressure **Min Pressure**	20-200mmHg (Tolerance:±20mmHg)	30-240mmHg (Tolerance:±20mmHg)	Different The minimum and maximum pressure level of the subject is significantly lower than the predicate device, so there is no safety issue concerned and as for the efficacy, it remains valid since its performance has been demonstrated by the performance testing data included in this submission.
Number of Chambers	4 Chambers	6 chambers	Different The "applicable treatment site" and "usage instructions" of the subject device fall within the same range

Device	Subject Device (-)	Predicate device（K243320）	SE discussion
			as the predicate device, these differences do not impact safety and effectiveness.
Power consumption	30w	35w	Different There is a difference in the power of the heating device between the subject device and the predicate devices. However, while having lower power than equivalent devices is safe.
Size	Size 285*90*90mm 	Size 220*140*90mm 	Different The size and weight differences of the equipment do not affect its safety and effectiveness.
Product Weight	1.6 kg	1.5 kg	
Body area specific cuffs	Leg Cuff: S:90×30cm L:110×30cm XL:110cm×35cm XXL:110cm×40cm XXXL:110cm×50cm 	Leg Cuff: M: 91cm×65cm L: 100cm×74cm XL:110cm×70cm(Overlapping) XXLP:120cm×70cm(Overlapping) XXL:125cm×74cm(Overlapping) 	Different Size and appearance of cuffs: Slight differences of size and appearance of the sleeves do not raise any safety or efficacy issues.

Device	Subject Device (-)	Predicate device（K243320）	SE discussion
Work mode	Mode 1: 10 seconds per phase  Mode 2: 10 seconds per phase  Mode 3: 10 seconds per phase  Mode 4: 10 seconds per phase  Mode 5: 10 seconds per phase  Mode 6: Mode1->Mode2->Mode3->Mode4->Mode5. The above 5 mode cycles take turns	Mode A: In this mode, only a single chamber is inflated at a time. Starting from the chamber ①and 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 ②inflates & deflates 4 times, both chamber ①② hold pressure; Chamber ③ inflates & deflates 4 times, both chamber ②③ hold pressure, chamber ① deflates; chamber ④ inflates & deflates 4 times, both chamber ③④ hold pressure, chamber ② deflates; working as this way up to chamber ⑥ . Then the cycle repeats. Remark: Under this mode, for the first cycle, it works as mode B to pre-run; 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.	There is no difference in the way the air pressure drops, and the next cycle begins. Since the treatment area is the same, these differences do not impact safety and effectiveness.

Device	Subject Device (-)	Predicate device（K243320）	SE discussion
			
Safety feature	Power button on main unit allows stop therapy session at any time.	Power button on main unit allows stop therapy session at any time.	Same
Technology	Compressor and valve system which inflates inflatable chambers sequentially.	Compressor and valve system which inflates inflatable chambers sequentially.	Same

H. Performance characteristic

The Intermittent Compression System (Compression Pump, PT1005A; Compression Leg Cuffs, L-1001S, L-1001L, L-1001XL, L-1001XXL, L-1001XXXL) has been tested and met the requirements of the following standards:

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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

IEC 60601-1-11 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

I. Conclusion

This proposed device and the predicated products have similar intend use, device hardware design and device capabilities and performance. To ensure all the key characteristics of the products can meet the requirements, testing was performed and results demonstrated that the Intermittent Pressure Compression System is as safe and effective as the predicate device.

Based on the analysis above, we confirm that the subject device is substantially equivalent

to the predicate device.