July 27, 2026

Xiamen High Top Electronic Technology Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Rm. 1509, Jingting Bldg., Dongzhou Community, Guangming St., Guangming District
Shenzhen, Guangdong 518100
China

Re: K260529
Trade/Device Name: Air Compression Massager (HY-1165)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 25, 2026
Received: June 25, 2026

Dear Reanny Wang:

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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.07.27
21:26:04 -04'00'

for Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
Team Title
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.	K260529

Please provide the device trade name(s).

Air Compression Massager (HY-1165)

Please provide your Indications for Use below.

The air compression massager is an air pressure massager 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 (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

Traditional 510(k) Summary

1. Information of Submitter and Correspondent

Submitter's information:

Manufacturer Name:	Xiamen High Top Electronic Technology Co., Ltd.
Address:	F2-5, No.118 Siming Garden, Tong'an Industrial Park, Xiamen City, Fujian Province, China
Contact Person:	Haiou Liang
Contact Title:	Management Representative

Date Prepared: Jun. 18, 2026

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd
Address: Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen 518107, China
Contact Person: Reanny Wang
E-mail: reanny@reanny.com
Phone: +86(755) 27391220

2. Device Information

Trade Name:	Air Compression Massager
Model:	HY-1165
Common Name:	Powered Inflatable Tube Massager
Classification Name:	Massager, Powered Inflatable Tube
Regulation Number:	890.5650
Product Code:	IRP
Classification:	Class 2
Regulation Medical Specialty:	Physical Medicine

3. Identification of Predicate Device(s)

	Primary predicate device	Secondary predicate device
Manufacturer:	Rapid Reboot Recovery Products, LLC	NormaTec Industries, LP
Device name:	Rapid Reboot Compression Therapy System	Normatec Go
510(k) number:	K182668	K221666
Product code:	IRP	IRP
Regulation Number:	890.5650	890.5650
Classification:	2	2

4. Description of Device

Air compression massager is a powered inflatable tube massager. It is consisting of control unit, sleeves (include leg wraps, hip wraps and arm wraps), hose and power adapter. One end of the hose is connected to the host and the other to the wraps. 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 microprocessor. This microprocessor is to control the timing and the pressure reflected by the sensor, it cycles the airflow to reach the function of cycling compression of body parts, help 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.

Indications for Use

The air compression massager is an air pressure massager 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.

Intended Use Environment

Clinics, hospital, athlete training, and home environments.

5. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

5.1 Non-Clinical testing

A series of safety and performance tests were conducted on the subject device, including:

- Product service life
- Software validation
- Electromagnetic compatibility and electrical safety
- Bench performance testing, including maximum pressure testing (for pressure accuracy and sleeve integrity against rupture or leakage) and failure mode testing

All the test results demonstrate Air compression massager meets the requirements of its pre-defined acceptance criteria and intended use, and it is substantially equivalent to the predicate devices.

5.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.3 Animal testing

There was no animal testing.

6. Performance Summary

The devices conform to applicable standards as follow table:

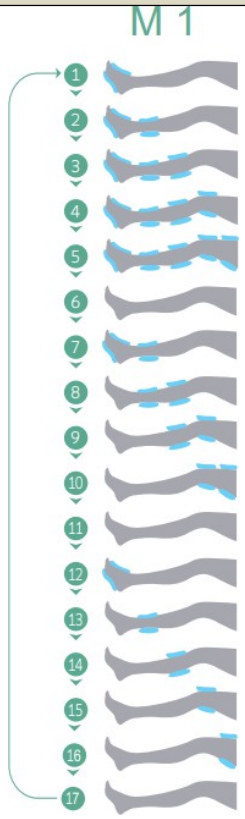
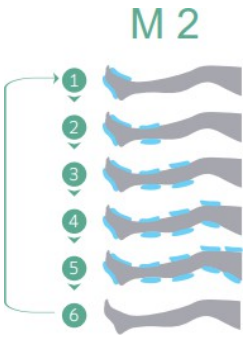
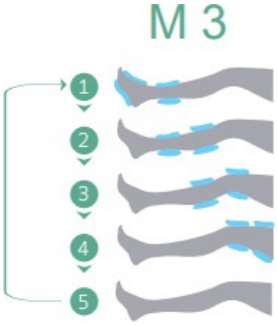
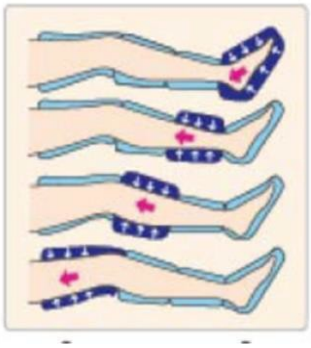
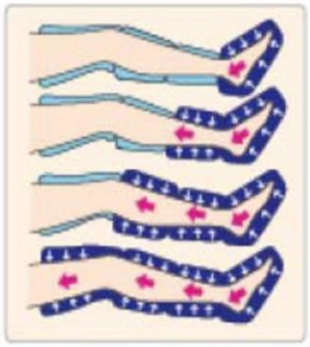
Test Type	Standard Designation Number	FDA recognition Status	Outcome for Device
Safety	ANSI AAMI ES60601-1:2005/ (R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	YES	Conforms
EMC	IEC 60601-1-2:2020 IEC TS 606011-4-2:2024	YES	Conforms
Home healthcare environment	IEC 60601-1-11:2020	YES	Conforms
Performance	Enterprise-specific testing, including: - Maximum pressure testing, for pressure accuracy and sleeve integrity against rupture or leakage - Failure mode testing	N/A	Conforms
Biocompatibility	Established via use of low-biocompatibility-risk materials identified in Attachment G of FDA's 2023 Biocompatibility Guidance	N/A	Conforms
Software	IEC 62304:2006+ A1:2015	YES	Conforms
Lithium battery	IEC 62133-2:2017	YES	Conforms

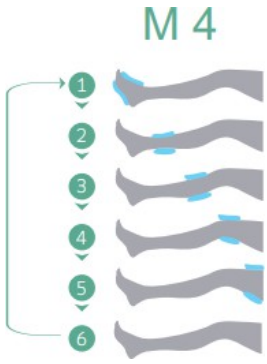
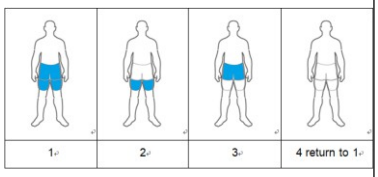
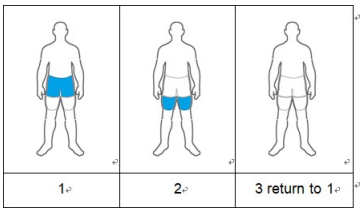
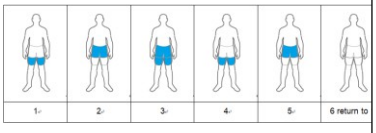
7. Discussion of Comparison to Predicate Devices.

Device	Subject Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Xiamen High Top Electronic Technology Co., Ltd.	Rapid Reboot Recovery Products, LLC	NormaTec Industries, LP
510(k) Number	K260529	K182668	K221666
Model Name	Air Compression Massager	Rapid Reboot Compression Therapy System	Normatec Go
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21CFR890.5650)
Indications for Use/Intended use	The air compression massager is an air pressure massager 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.	The Rapid Reboot Compression Therapy System is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	The Normatec Go is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.
Treatment area	Leg (including of feet, calves and thighs) Hip (including of upper leg, glutes, hips, lower back) Arm (consisting of entire arm, shoulder)	Leg (consisting of foot, calf, knee, upper leg) Hip (consisting of upper legs, glutes, hips, lower back) Arm (consisting of entire arm, shoulder, upper chest and back)	Calf
OTC or Rx	OTC	OTC	OTC
Environment of Use	Clinics, hospital, athlete training, and home environments.	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments
Power Source (battery charger)	INPUT:100-240VAC, 50/60Hz, 0.6A OUTPUT:DC 13.0V,1.8A	110V, 60Hz	Charging via 5 VDC compliant power supply (100- 240 VAC input) Powered by Integrated rechargeable battery

Device	Subject Device	Primary Predicate Device	Secondary Predicate Device
Therapy Time	10~60 minutes	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	Stays on until the user turns it off or can be set up to turn off in a range of 15 minutes to 60 minutes
Number of Chambers	5 chambers for leg wraps 5 chambers for arm wraps 2 chambers for hip wraps	4	3
Power consumption	23.4W	30W	Not publicly available
Battery	Internal battery: 11.1V, 3200mAh	Not publicly available	Internal battery 3.6V, 2550mAh Internal batter y (D610-1-d1-1S1P) 3.65V, 2600mAh
Inflation time	30s-180s Stop inflating when the setting pressure level is reached.	Not publicly available	Not publicly available
Deflation time	16s-41s	Not publicly available	Not publicly available
Hold time	3s-16s	Not publicly available	Not publicly available
Cycle time	136s-604s	1 min 20 sec	Not publicly available
Interval time	6s-15s	Not publicly available	Not publicly available
Contact Surface Material	Nylon , Polyethylene Terephthalate (PET)	Nylon with a Polyurethane laminate	200 denier nylon with a polyurethan e aminate/extrusion
Housing Materials And Constructions	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure

Device	Subject Device	Primary Predicate Device	Secondary Predicate Device
Patient contact	Non-conductive attachments	Non-conductive attachments	Non-conductive nylon containing air bladders that when secured around the calf by Velcro, form zones of air tubes for compression
SW/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	Microprocessor
Mode of compression	Sequential/Peristaltic	Sequential/Peristaltic	Sequential Gradient, Peristaltic and Pulsing
Output pressure range	0~190 mmHg	0~200mmHg	0~220mmHg
Air pressure level/ Compression levels	4 levels setting: Level 1: 75 mmHg Level 2: 115 mmHg Level 3: 150 mmHg Level 4: 190 mmHg	Not publicly available	Level I:40-70mmHg Max Level 2:60-90mmHg Max Level 3:80-110mmHg Max Level 4:100-140mmHg Max Level 5:130-170mmHg Max Level 6:150-200mmHg Max Level 7:180-220mmHg Max
Work mode	There are 5 modes for leg wraps and arm wraps, 3 modes for hip wraps ● For leg/arm wraps: Here are the details of the five modes of chamber inflation for the legs and arms M1 is a combination of M2,M3 and M4 M1 follows this pressure sequence:	2 modes: “A” mode inflates and deflates chambers from bottom up (distal to proximal chambers),one at a time. “B” mode also inflates chambers 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. Mode A:	Not publicly available

Device	Subject Device	Primary Predicate Device	Secondary Predicate Device
	 M2 follows this pressure sequence:  M3 follows this pressure sequence: 	 Mode B: 	

Device	Subject Device	Primary Predicate Device	Secondary Predicate Device
	M4 follows this pressure sequence:  M5 follows this pressure sequence:  ● For hip wraps: M1 follows this pressure sequence: M1:  M2 follows this pressure sequence: M2:  M3 follows this pressure sequence: M3:  		

Device	Subject Device	Primary Predicate Device	Secondary Predicate Device
Size and appearance	233mm x 109mm x 92mm 	10” x 6.5” x 5” 	Not publicly available
Weight	6.8 kg with all attachments	5.8 pounds	1.2 lbs
Size and appearance of sleeves (leg part)	1080mm x 385mm 	X-Short: 14” x 41” Short: 14” x 43” Medium: 14” x 45” Long: 14” x 48” X-Long: 14” x 52” 	Not publicly available
Size and appearance of sleeves (hip part)	1020mm x 530mm 	Regular: 26” x 32” Large: 26” x 35” 	Not publicly available
Size and appearance of sleeves (arm part)	2000mm x 325mm 	Regular: 18” x 38” Long: 18” x 44” 	Not publicly available
Safety Features	Button on display allows user to stop or pause therapy session at any time	Button on display allows user to stop or pause therapy session at any time.	Not publicly available
Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.
Standards	ANSI - AAMI ES 60601 – 1 IEC 60601-1-2 IEC TS 60601-4-2 IEC 60601-1-11	IEC 60601-1:2014; IEC 60601-1-2:2014; EN ISO 10993-5:2009 & EN ISO 10993-10:2010	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 ANSI C63.27-2017

8. Conclusions

The Air compression massager has been compared with Rapid Reboot Compression Therapy System (K182668) and Normatec Go (K221666). The subject device has the same intended use and similar technological characteristics as those of the predicate devices. Although there are several specifications that are different among the subject device and predicate devices , the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test criteria. Therefore, the differences do not raise any concerns with respect to substantial equivalence. The differences in technological characteristics do not raise different questions of safety and effectiveness, and based on the testing submitted to support this submission, the subject device is substantially equivalent to the predicate devices.