November 13, 2025

Shenzhen Future Electronic Co.,Ltd.
% Xiongxiu Zhou
Official Correspondent
Shenzhen Reanny Medical Devices Management Consulting Co. Ltd
Room 1509, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518107
China

Re: K251662
Trade/Device Name: Air Compression Therapy Device (ST-504); Air Compression Therapy Device (ST-505); Air Compression Therapy Device (ST-506); Air Compression Therapy Device (ST-507)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, IRT, IRO
Dated: October 14, 2025
Received: October 14, 2025

Dear Xiongxiu Zhou:

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

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.	K251662

Please provide the device trade name(s).

Air Compression Therapy Device (ST-504);
Air Compression Therapy Device (ST-505);
Air Compression Therapy Device (ST-506);
Air Compression Therapy Device (ST-507)

Please provide your Indications for Use below.

The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.

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)

K251662

510(k) Summary

Type of 510(k) submission: Traditional

Date prepared: Nov. 13, 2025

Submitter's information

Submitter	Shenzhen Future Electronic Co.,Ltd.
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Application Correspondent

Company	Shenzhen Reanny Medical Devices Management Consulting Co.,Ltd.
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Device Identification

Trade Name	Air Compression Therapy Device (Models: ST-504, ST-505, ST-506, ST-507)
Regulation Number	21 CFR 890.5650
Classification Name	Massager, Powered Inflatable Tube
Device Classification	Class II
Panel	Physical Medicine
Product Code	IRP, IRT, IRO
Previous Submissions	None

Indications for use

The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.

Device Description

The Air Compression Therapy Device is a powered inflatable tube massager. It is mainly composed of controller or main unit (including Lithium-ion Battery Pack), sleeve and Type-C USB charging cable. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment. The devices are powered by an internal IEC 62133-2 compliant lithium-ion battery.
The user interface on the Air Compression Therapy Device is a series of buttons with a small display screen to display the air pressure level, massage mode,heating intensity level, vibration intensity level,battery level display and massage area display.
The air compressor inflate the air into the air chamber, the increased air pressure in air chamber act on the limbs and cause the limb tissue to be pressed. Then deflating the air to relax the limb tissue. 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 air is inflated / deflated orderly from distal to proximal limbs. These action simulating kneading and stroking of limb tissues to achieve the purpose of temporary relief of minor muscle aches and pains and temporary increase in circulation to the treated areas.

Predicate Device Information

Sponsor	Shenzhen Ruiyi Business Technology Co.,Ltd.
Trade/Device Name	Leg Massager (Models:RP-ALM070H,RP-ALM071H)
510(k) Number	K232965
Regulation Number	21 CFR 890.5650

Sponsor	Therabody, Inc.
Trade/Device Name	JetBoots PRO Plus
510(k) Number	K241256
Regulation Number	21 CFR 890.5650

Basic technological characteristics. New devices VS Predicate devices

Table 1A:Summary of comparison

Device	Subject device	Predicate device	Reference Device	Comparison
Manufacturer	Shenzhen Future Electronic Co.,Ltd.	Shenzhen Ruiyi Business Technology Co.,Ltd.	Therabody,Inc.	N/A
510(K) number	Pending	K232965	K241256	N/A
Product name	Air Compression Therapy Device	Leg Massager(Models:RP-ALM070H,RP-ALM071H)	JetBoots PRO Plus	N/A
Models	ST-504,ST-505,ST-506,ST-507	RP-ALM070H,RP-ALM071H	JetBoots PRO Plus	N/A
Product regulation	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	Same
Classification name	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Same
Regulation class	2	2	2	Same
Indications for Use (IFU)	The Air Compression Therapy Device is indicated for the	Leg Massager (Models:RP-ALM070H,RP-ALM071H) is	JetBoots PRO Plus is an air compression therapy device	Note 1 Similar.

Device	Subject device	Predicate device	Reference Device	Comparison
	temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.	intended for home 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 to provide graduated pressure to the legs. JetBoots Plus is indicated for the temporary relief of minor muscle aches and pains, and for a temporary increase in blood circulation to the treated area in people who are in good health. JetBoots PRO Plus simulates kneading and stroking of tissues by using an inflatable garment	The subject device and reference device has heating mode and vibration mode as auxiliary functions. The predicated device only has heating mode
OTC or Rx	OTC	OTC	OTC	Same
Classification Product Code	IRP,IRT,IRO	IRP,IRT	IRP, ILY, IRO	Similar
Pressure range	0~165mmHg	0~240mmHg	20-100mmHg,steps of 5mmHg	Note 3 Different

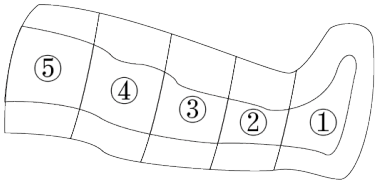
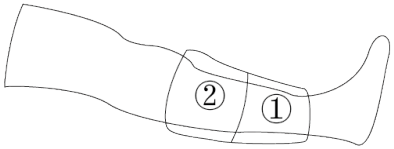
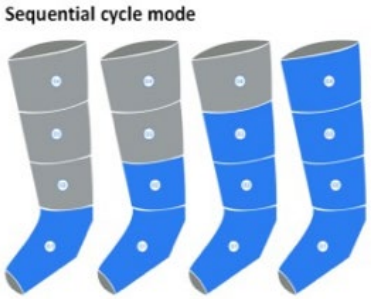
Device	Subject device	Predicate device	Reference Device	Comparison
Inflation time	10-240s	3-30s	Information not available in 510(K) summary	Note 3 Different
Deflation time	5-10s	1-5s	Information not available in 510(K) summary	Note 3 Different
Treatment time	20minutes±30s	20 minutes	10min-60min,steps of 5min for Pneumatic Compression 10min-45min for Infrared LED	Same
Mode of compression	Sequential	Sequential	Sequential	Same
Power source	No adaptor provided 5 VDC via an IEC 60601-1 compliant power supply(100-240 VAC input) Integrated rechargeable battery	100~240V 50/60Hz	Power Adaptor: AC Input:100-240V AC, 50/60Hz, DC Output: 15.0V, 4.8A, 72W Or Internal Battery	Note 2 Similar
Power consumption	10W	24W	72W	Note 2 Different
Size and	ST-504:340*840mm	Thighs:	Compression boots sleeves attached to consoles.	Note 4

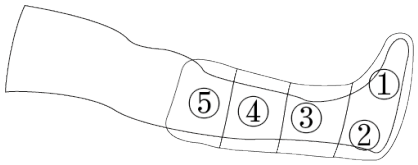
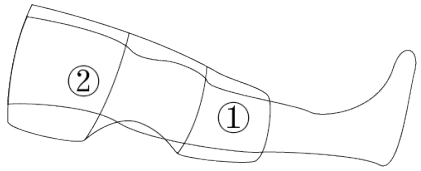
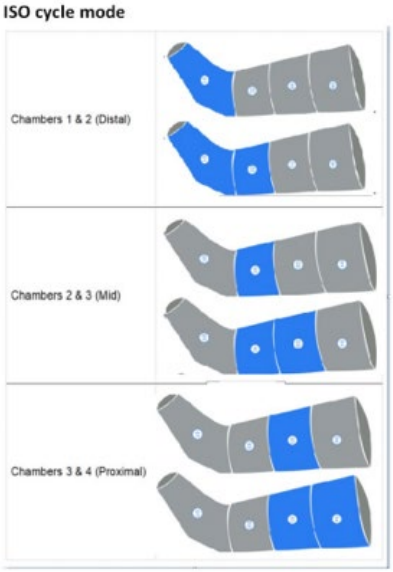
Device	Subject device	Predicate device	Reference Device	Comparison
appearance of sleeves(leg part)	ST-505:610*321mm ST-506:300*480mm ST-507:730*550mm	One size:11*16*24.9inch+8*33.5inch =279.4mm*406.4mm*632.46mm+203.2mm*850.9mm	Sleeves(extended) only: S:80cm(L)*37.5cm(H)=800mm(L)*375mm(H) M:95cm(L)*41.0cm(H)=950mm(L)*410mm(H) L:1050cm(L)*41.0cm(H)=10500mm(L)*410mm(H)	Different

Device	Subject device	Predicate device	Reference Device	Comparison
Photo	ST-504:  ST-505:  ST-506:	RP-ALM070H  RP-ALM071H 	Information not available in 510(K) summary	Note 4 Different

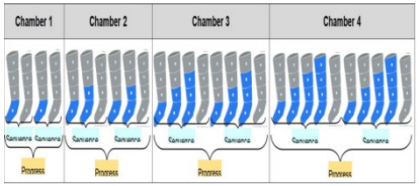
Device	Subject device	Predicate device	Reference Device	Comparison
	 ST-507: 			
Housing materials	Molded PC+ABS enclosure	Molded ABS enclosure	Molded PC+ABS Enclosure	Same

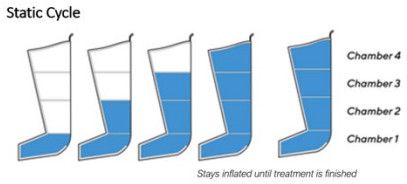
Device	Subject device	Predicate device	Reference Device	Comparison
Number of chambers	ST-504:5 chambers ST-505:2 chambers ST-506: 5 chambers ST-507: 2 chambers	3 chambers	4 chambers	Note 3 Different
Work mode	Sequence mode: it helps relaxing muscles with various combination massage movements mainly using a single chamber inflation; Circulation mode: it helps relaxing muscles through a variety of combined massage movements, mainly by inflating two chambers simultaneously; Whole mode:it has combined functions, which includes multiple combination massage actions	RP-ALM070H: Six models (3 combine massage modes and 3 Separate Massage Modes) C1: Massage full legs. C2: Massage feet and calves. (It can be used individually, and don’t need to connect the air hose of thighs wraps.) C3:Massage feet, calves, thighs by turn. It will be turn off When you press the Button C again.	Sequential,ISO,or Static Flow Cycles Sequential mode that applies a directional massage, starting at the base of the treated area,and progresses upwards towards the torso and then releases.	Note 5 Different

Device	Subject device	Predicate device	Reference Device	Comparison
	such as single, two, and three chambers inflation. Work flow:①~⑤Indicate the airbag number for the current inflation step,⓪indicating all airbags are deflated. ST-504:  ST-505:  ST-506:	T: Massages thighs C: Massages calves F: Massages feet. It will be turn off when you press the Button S again. RP-ALM071H: Five models(3 combine massage modes and 2 Separate Massage Modes)： Combine 1: Massage feet and calves Combine 2: Massage from calves to feet Combine 3: Massage from feet to calves Press it again to turn off combine message function.	 ISO mode that applies a directional massage to a smaller, user-selected area. The first chamber inflates,and after a few seconds, the second chamber starts to inflate until both chambers reach the set pressure. The both chambers deflate, and after a pause the process starts again.	

Device	Subject device	Predicate device	Reference Device	Comparison
	 ST-507:  Sequence mode ST-504:①→⓪→②→⓪→③→⓪→④→⓪→⑤→⓪→①→⓪→①②→⓪→①②③→⓪→①②③④→⓪→①②③④→⓪ ST-505:①→⓪→②→⓪→①→⓪→②→⓪→①→①②→⓪→①	F: Massage feet. C:Massage calves. Press it again to turn off separate massage function.	 Flow cycles Progress1:first inflate Chamber 1 to target pressure, then hold & release, then go to Progress 2: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. When Chamber 2 reach the target pressure,hold chamber 1&2 for specified time, then release	

Device	Subject device	Predicate device	Reference Device	Comparison
	→①②→⓪→①②→⓪→①→⓪ →①②→①→⓪→①②→②→⓪ →①②→⓪ ST-506: ①②→③→④→⑤→⓪ →①②→①②③→③④→④⑤→ ⑤①②→①②③→③④→④⑤→ ⑤→⓪→①②→①②③→①②③ ④→①②③④⑤→⓪→①②③④ ⑤→→③④⑤→④⑤→⑤→⓪→ ①②③④⑤→⓪ ST-507:①→⓪→②→⓪→①→ ⓪→②→⓪→①→①②→⓪→① →①②→⓪→①②→⓪→①→⓪ →①②→①→⓪→①②→②→⓪ →①②→⓪ Circulation mode ST-504:①→①②→①②③→①②		totally, then go to Progress 3. Progress 3: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. When Chamber 2 reach the target pressure, hold chamber 1 & 2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, the hold chamber 1,2,3 for specified time then release totally.The go to Progress 4. Progress 4: first inflated Chamber 1 to target pressure, then inflate Chamber 2 and hold Chamber 1. When Chamber 2 reach the target pressure, hold chamber 1&2, & start to inflate Chamber 3, when Chamber 3 reach to the target pressure, then hold chamber 1,2,3,& start to inflate Chamber 4, when Chamber 4 reach to the target pressure, then hold chamber	

Device	Subject device	Predicate device	Reference Device	Comparison
	③④→①②③④⑤→⓪ ST-505:①→②→①→②→①→②→⓪→①→①②→⓪→②→①→⓪→①②→⓪ ST-506: ①②→①②③→①②③④→③④⑤→④⑤→⑤→⓪→①②→①②③→①②③④→①②③④⑤→③④⑤→④⑤→⑤→⓪→①②→⓪→①②③→⓪→①②③④→⓪→①②③④⑤→⓪→①②③④⑤→①②③④→①②③→①②→⓪ ST-507: ①→②→①→②→①→②→⓪→①→①②→⓪→②→①→⓪→①②→⓪ Whole mode ST-504:Sequence		1,2,3 & 4 for specified time then release totally. Then go back to Progress 1 again.  Static Cycle The chambers inflate one at the time starting at chamber 1 while maintaining negative gradient of compression along the leg. The pressure is limited to 20mmHg to 30mmHg. Once inflated, the chambers do not deflate during the treatment. While the garment is inflated, it comes in contact with the legs to optimize the treatment of vibration and infrared LED light by ensuring optimal contact with the leg.	

Device	Subject device	Predicate device	Reference Device	Comparison
	mode+Circulation mode ST-505:Sequence mode+Circulation mode ST-506: ①②→③→④→⑤→⓪ →①②→①②③→③④→④⑤→ ⑤①②→①②③→③④→④⑤→ ⓪→①②→①②③→①②③④→ ①②③④⑤→①②③④→①②③ →①②→⓪→①②③④⑤→③④ ⑤→④⑤→⑤→⓪→①②③④⑤ →⓪ ST-507: Sequence mode+Circulation mode□			
Safety feature	Button on display allows user to stop therapy session at any time	Button on display allows user to stop or pause therapy session at any time	Information not available in 510(K) summary	Same

Device	Subject device	Predicate device	Reference Device	Comparison
Technology/Device Function	Compressor and valve system which sequentially inflates inflatable chambers	Compressor and valve system which sequentially inflates inflatable chambers	Compressor and valve system which sequentially inflates cells of appliance,Light Emitting Diodes	Same
Operating environment	Temperature: 5℃~35℃ Relative Humidity:15-90%, non-condensing Atmospheric pressure:70kPa-106kPa	Temperature:5-40℃, Humidity:15%-90%	Information not available in 510(K) summary	Similar
Transportation and Storage environment	Temperature: -10℃~45℃ Relative Humidity:5-90%, non-condensing Atmospheric pressure:70kPa-106kPa	Temperature:-25-70℃, Humidity:15%-90% non-condensing Atmospheric pressure:75kPa-106kPa	Information not available in 510(K) summary	Similar
Heat therapy	Not exceeding 45℃ H1: 36℃±2℃	Not exceeding 45℃	Maximum Device Surface	Same

Device	Subject device	Predicate device	Reference Device	Comparison
	H2: 38℃±2℃ H3: 40℃±2℃		Temperature:43.2℃ Highest Measured Skin Temperature During Treatment: 36.8℃	
Number of patients that can be treated at one time	One	One	One	Same
Static or Intermittent Pressure	Both	Both	Information not available in 510(K) summary	Same
Power down	Available	Available	Information not available in 510(K) summary	Same
Heating Mechanism	Thermotherapy	Thermotherapy	Infrared LED light therapy	Same
User Interface	Touch Screen	Touch Screen	Information not available in 510(K) summary	Same

Device	Subject device	Predicate device	Reference Device	Comparison
Types of garments	ST-504:Sleeve for thighs, knees, calves and feet ST-505:Sleeve for calves ST-506:Sleeve for knees, calves and feet ST-507:Sleeve for thighs, knees and calves	Sleeves for thighs,calves, and feet	Sleeves for Legs and feet	Similar
Patient Contacting Material	All encompassed with a Nylon with a Polyurethane laminate material	All encompassed with a Nylon with a Polyurethane laminate material	Polyether Nylon Fabric	Same
Multi-Patient Use and Single Patient Use Wraps	Multi-Patient Use	Multi-Patient Use	Information not available in 510(K) summary	Same
Sterility	Non-sterile only	Non-sterile only	Non-sterile only	Same
Expected life of garments	Based on frequency of use and continued functional performance	Based on frequency of use and continued functional performance	Information not available in 510(K) summary	Same

Device	Subject device	Predicate device	Reference Device	Comparison
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC TS 60601-4-2 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC TS 60601-4-2 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 ANSI C63,18 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-83 IEC 62133-2 IEC 62304 IEC 62471 IEC 60601-2-57 ISO 10993-5 ISO 10993-10 ISO 10993-23	Note 6 Minor different.

Comparison discussion

Note 1:
The subject device has the intended use as same as the predicate device (K232965) and reference device (K241256). According to the 510(k) summary of predicate device(K232965), it has air compression and heating therapy only, while the reference device (K241256) has air compression, Infrared LED heat therapy and therapeutic vibration function. The type of use of the subject device is same to the predicate device and reference device. The temperature of heat therapy of the devices are not exceeding 45℃, which complied to the safety and effectiveness.

Note 2:
The output of power source are different in current and power consumption among the devices. The subject device is powered by an internal rechargeable battery, with a Type-C USB charging cable only, no external DC Power Adaptor is provided by manufacturer. The predicate device (K232965) is powered by an external DC Power Adapter. The JetBoots PRO Plus boots (reference device, K241256) are powered by an internal rechargeable battery or by an external DC Power Adapter, plugged into a wall electrical outlet. The batteries are located inside each console and can be charged before the device operates. They are all complied with IEC 60601-1， IEC 60601-1-2 and IEC60601-1-11, the safety and effectiveness of the subject device is verified via tests, so the differences do not affect the safety and effectiveness.

Note 3:
From the comparison table above, the device design among the predicate device, reference device and subject device are mainly equivalent, the specifications of subject device are not completely same among them. The Pressure range, Inflation time, Deflation time, number of chambers, working mode of subject device are similar or a bit different to the predicate device and reference device. The key parameters for the safety and effectiveness of the air compression therapy device are pressure range and temperature of thermal therapy. The safety and effectiveness of the subject device and reference device are verified via tests according to IEC 60601-1,IEC 60601-1-2, IEC 60601-1-11, non-clinical performance bench testing, so the differences do not affect the safety and effectiveness.

Note 4:
The "Size and appearance of sleeves (leg part)", is belonging to basic physical characteristics. Although it is a bit different from the predicate device, it will not affect the main function and the intended use of the device. They all also comply with IEC 60601-1 requirements. Besides, the subtle change of the physical characteristics will not affect the critical functions or normal use, and not raise any safety or effectiveness issues.

Note 5:

Although the subject device provides 3 working modes, which are not completely the same as the predicate device with six modes or five modes, the predicate device only shows the differences in treatment area when switching the modes. The treatment area of subject device are varied due to different models, thus all the models of subject device can cover the treatment area presented by the predicate device. The subject device has similar working flow compared to the reference device. The treatment pressure range of subject device and predicate are the same under different modes, thus different modes would not impact safety and effectiveness.

Note 6:

The “standards” of subject device is same with predicate device but minor different to the reference device. The subject device and predicate device have no LED Strips, thus no safety requirement for IEC 62471, IEC 60601-2-83 and IEC 60601-2-57. Therefore, this difference will not raise any safety or effectiveness issue.

Summary of the technological characteristics of the device

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 +A1:2020 - 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
- IEC TS 60601-4-2-Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO 10993-5: 2009 - Biological Evaluation of Medical Device - Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10: 2021 - Biological Evaluation of Medical Devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021- Biological Evaluation of Medical Devices - Part 23: Tests for irritation
- 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

The following additional performance bench testing was conducted:
- Accuracy for Pressure Testing
- Accuracy for Temperature Testing
- Accuracy for Vibration Testing
- Mechanical safety valve testing
- Seam Strength Testing
- Failure Mode Testing

Conclusion

Air Compression Therapy Device is substantially equivalent to the Predicate Device and the Reference Device in Indications for Use and technological characteristics. Though minor differences exist among the Proposed, Predicate, and Reference devices, these do not raise questions of safety and effectiveness. Therefore, Air Compression Therapy Device is as safe, as effective, and performs as well as the Predicate and Reference Devices.