February 19, 2025

Sichuan Qianli-beoka Medical Technology Inc.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Mgmt Consulting Co., Ltd
Room 1509, Jingting Building, Dongzhou Community
Guangming Street, Guangming District
Shenzhen, Guangdong
China

Re: K243206
Trade/Device Name: Air compression massager (ACM-PLUS-A1, ACM-PLUS-A2, ACM-PLUS-A3, ACM-PLUS-A4, ACM-PLUS-A5, ACM-PLUS-A6)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 23, 2024
Received: October 1, 2024

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 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,

Heather L. Dean -S

Heather Dean, PhD
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)*

K243206

Device Name

Air compression massager (ACM-PLUS-A1, ACM-PLUS-A2, ACM-PLUS-A3, ACM-PLUS-A4, ACM-PLUS-A5, ACM-PLUS-A6)

Indications for Use *(Describe)*

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.

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.

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Traditional 510(k) Summary
K243206

1. Information of Submitter and Correspondent

Submitter's information:

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Contact Title: Management representative

Contact Email: caiqiuju@beoka.com

Date Prepared: Sep. 23, 2024

Submission correspondent's information:

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Contact Person: Reanny Wang

E-mail: reanny@reanny.com

Phone: +86(755) 27391220

2. Device Information

Trade Name: Air compression massager

Model:	ACM-PLUS-A1, ACM-PLUS-A2, ACM-PLUS-A3, ACM-PLUS-A4, ACM-PLUS-A5, ACM-PLUS-A6
Common Name:	Powered Inflatable Tube Massager
Classification Name:	Massager, Powered Inflatable Tube
Regulation:	21 CFR § 890.5650
Device Class:	Class 2
Product Code:	IRP

3. Identification of Predicate Device(s)

Manufacturer	NormaTec Industries, LP	Theragun Inc
Legally Marketed Device	Normatec Elite	RecoveryAir PRO
510(K) Number	K240122	K211745

4. Description of Device

The Air compression massager is a powered inflatable tube massager. It is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. It simulates manual kneading and stroking of tissues by the use of an inflatable pressure cuff. The devices are to be used by people who are in good health. The devices are powered by an internal IEC 62133-2 compliant lithium-ion battery.

The user interface on the Air compression massager is a series of buttons with a small display screen to display the treatment time, pressure level, mode and chamber status. The user interface provides for:

· Starting and stopping the massage treatment;

· Adjusting treatment related parameters such as treatment time and pressure level etc.;

· Selection of the chamber to boost the pressure.

In addition to the user interface on the devices, the subject device have Bluetooth capability that allows the use of a Beoka 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 listed above for convenience.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

All models in this submission are the same except for the color of controller and button shape.

5. 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.

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

6.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Product service life
- Software validation
- Electromagnetic compatibility and electrical safety
- Function test
- Wireless Coexistence

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.

6.2 Clinical Testing

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

7. 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 60601-4-2: 2024	Yes	Conforms
Home healthcare environment	IEC 60601-1-11:2020	Yes	Conforms
Performance	Enterprise standard	Yes	Conforms
Biocompatibility	ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2021; ISO 10993-23: 2021.	Yes	Conforms
Software	ANSI AAMI IEC 62304:2006/A1:2016	Yes	Conforms
Lithium battery	IEC 62133-2: 2017	Yes	Conforms
Wireless Coexistence	IEEE ANSI USEMCSC C63.27-2021 AAMI TIR69:2017/(R2020)	Yes	Conforms

8. Discussion of Comparison to Predicate Devices.

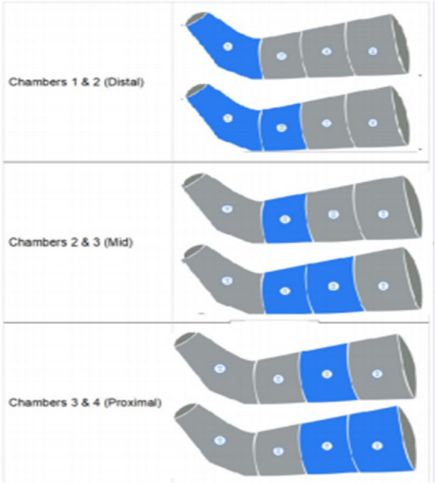
The Air compression massager submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics and performance to the cleared Normatec Elite **K240122** and RecoveryAir PRO **K211745**. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

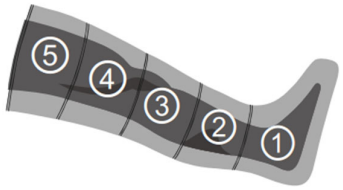
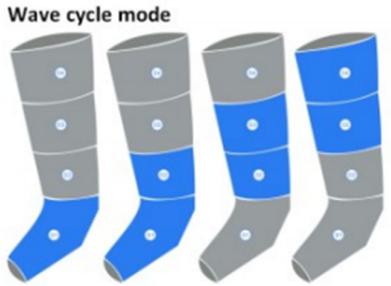
Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
Manufacturer	Sichuan Qianli-beoka Medical Technology Inc.	NormaTec Industries, LP	Theragun Inc	NA
Product name	Air compression massager (Model No.: ACM-PLUS-A1, ACM-PLUS-A2, ACM-PLUS-A3, ACM-PLUS-A4, ACM-PLUS-A5, ACM-PLUS-A6)	Normatec Elite	RecoveryAir PRO (Model RecoveryAir PRO)	NA
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Same
OTC or Rx	OTC	OTC	OTC	Same
Indications for Use (IFU)	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.	The Normatec Elite is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The RecoveryAir PRO is an air compression therapy device intended to provide graduated pressure to compression garments. The RecoveryAir PRO is indicated for the temporary relief of minor muscle aches and pains, and for temporary increase in blood circulation to the treated areas in people who are in good health. The RecoveryAir PRO simulates kneading and stroking of tissues by using an inflatable garment.	Same
Anatomical Coverage	Control unit mounted to inflatable segment with integral hoses.	Control unit mounted to inflatable segment with integral hoses.	Not publicly available	Same

Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
Intended Use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Not publicly available	Same
Power Source(s)	7.3 V / 2600mAh Rechargeable Li-ion battery	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Integrated rechargeable battery	100-240 V AC, 50/60 Hz, 12 V or internal battery.	Minor different Note 1
Software / Firmware Micro-processor Control	Microprocessor	Microprocessor	Microprocessor	Same
Technology	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Same
Output Pressure range	0 - 110 mm Hg	0 - 110 mm Hg	20-100mmHg	Same: the same as the primary predicate device
Pressure Levels	A total of 15 pressure levels, the lowest level is 40mmHg, 5mmHg increments	Level 1: 40 mm Hg Level 2: 50 - 60 mm Hg	Not publicly available	Minor different

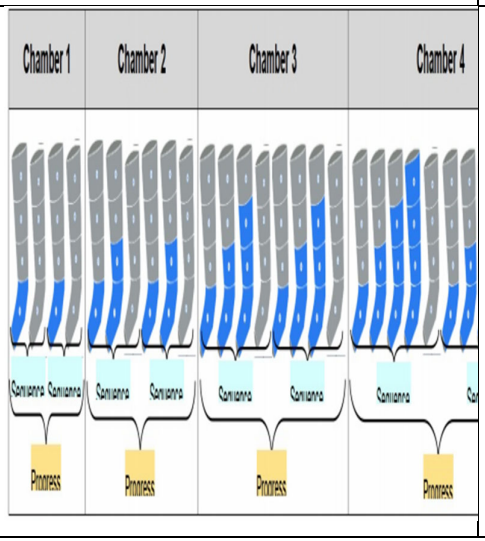
Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
	per level, and the highest level is 110mmHg	Level 3: 60 - 70 mm Hg Level 4: 70 - 80 mm Hg Level 5: 80 mm Hg Level 6: 80 - 90 mm Hg Level 7: 100 mm Hg		Note 2
Treatment Time	Can be set up to turn off in a range of 15 minutes to 60 minutes	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	10min-90min, step of 5min	Same: The same as the primary predicate device
Inflation/Deflation Cycle Type	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Same
Contact Surface Material	Nylon, TPU, metal, polyester fibre, PP	200 denier nylon with a polyurethane laminate/extrusion	Polyether Nylon Fabric	Different Note 3
Number of Inflatable segments	5 segments for leg attachment	5 segments for leg attachment	4 segments for leg attachment	Same: The same as the primary predicate device
Weight	S size: 3.2kg; M size:3.3kg; L size :3.5kg; XL: 3.7Kg	3.0 lbs	4.202 pounds	Minor different Note 1
Control Unit Dimensions	L173 X W100 X H52mm	3.5” x 1.75” x 7.0”(W x H x D)	8.6in (L) *6.7in (W) *5.1in (H)	

Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
Size of sleeves	S(L840xW330xH120)mm; M(L950 X W380 X H140)mm; L(L1020xW380xH150)mm; XL(L1100xW410xH150)mm	Not publicly available	RecoveryAir Compression Boots: 95*28.7 cm	
Housing Materials And Construction	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Same
Patient contact	Non-conductive wrap Surface Device Intact Skin	Non-conductive wrap Surface Device Intact Skin	Non-conductive appliances	Same
Modes (massage sequences)	A total of 5 mode can be selected: M1 Fatigue relief mode M2 Training activation mode M3 Workout recovery mode M4 Overall relaxation mode M5 Deep care mode **M1 Fatigue relief mode and M2 Training activation mode:** The Massage sequence: ①→① ②→① ② ③→① ② ③④→① ② ③④⑤ **M3 Workout recovery mode:**	Not publicly available	Sequential, ISO or Rehab (wave), Flow cycles **Sequential mode**: Sequential mode that applies a directional massage, starting at the base of the treated area, and progresses upwards towards the torso and then releases: **ISO mode:**	Minor different Note 4

Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
	①*→①②*→①②③*→②③④*→③④⑤* (The chamber marked with"*" means this chamber will be inflated-deflated for 3 times) **M4 Overall relaxation mode:** The default Massage sequence of one cycle: (①)×2→ (①→①②)×2→ (①→①②→①②③)×2→ (①→①②→①②③→①②③④)×2 → (①→①②→①②③→①②③④→①②③④⑤)×2 Under the default Massage sequence, each step is inflate-deflated for 2 times, which we call frequency 2. The frequency can be set to 1~5 through the APP: Frequency 1: each step is inflate-deflated for 1 time, and then go to the next step. Frequency 2: each step is inflate-deflated for 2 times,and then go to the next step. Frequency 3: each step is inflate-		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. Then both chambers deflate, and after a pause the process starts again  **Wave mode:** The first chamber inflates, and after a few seconds, the 1st and 2nd chamber starts to inflate until both chambers reach the set pressure. Then the deflation on 1st	

Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
	deflated for 3 times,and then go to the next step. Frequency 4: each step is inflate-deflated for 4 times,and then go to the next step. Frequency 5: each step is inflate-deflated for 5 times, and then go to the next step. **M5 Deep care mode** The Massage sequence: ①→②→③→④→⑤ Remark: ①,②,③,④ and ⑤ represent the first, second, third, fourth and fifth chambers from the distal end to the proximal end. 		chamber , the 2nd and 3rd chambers starts to inflate until the both chambers reach the set pressure; then deflate the 2nd chambers inflate 3rd and 4th chambers until the both chambers reach the set pressure  **Flow cycles:** Progress 1: first inflate Chamber 1 to target pressure, then hold & release. then go to Progress 2. 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 totally, then go to Progress 3	

Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
			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, then hold chamber 1, 2, 3 for specified time then release totally. then 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 1, 2, 3 &4 for specified time then release totally. then go back to Progress 1 again.	

Device	Subject device	Primary Predicate device (K240122)	Secondary predicate device (K211745)	Comparison
				

The discussion of differences exist between the subject and predicate devices is listed as follows:

Note 1:
Although the device design and specification parameter between the predicate devices and subject device are different, they are both complied with ANSI/AAMI ES60601-1. So the minor differences on such parameters (power source, Control Unit Dimensions ,Size of sleeves and weight) do not affect the safety and effectiveness.

Note 2:
Although the “pressure levels” of subject device is different from the predicate device, their output pressure range are the same, so the pressure level different do not affect the safety and effectiveness. Additionally, the subject device conforms to ANSI/AAMI ES60601-1, so the small differences do not affect the safety and effectiveness.

Note 3:
Although the “Contact Surface Material” is difference from that of predicate devices, both the Contact Surface Material of subject device and predicate devices comply with ISO 10993-5 and ISO 10993-10 and/or ISO -10003-23. Therefore, the difference would not raise adversely impact on safety and effectiveness.

Note 4:
The massage sequence of M1 Fatigue relief mode and M2 Training activation mode are similar to Sequential mode of secondary predicate device.

The massage sequence of M3 Workout recovery mode is similar to the Wave mode of secondary predicate device, both of them always keep several chambers in working status, the difference is that in the working chambers of M3 Workout recovery mode, the proximal working chamber will be inflated-deflated a total of three times. Due to the overall massage sequence of M3 Workout recovery mode and Wave mode are consistent, and the massage pressure range of subject device is within the range of predicate devices, so the small differences do not affect the safety and effectiveness.

M4 Overall relaxation mode: The massage sequence of M4 Overall relaxation mode is similar to the Flow cycles of secondary predicate device, their progress is consistent, with the only difference being that the frequency of the M4 Overall relaxation mode can be adjusted, so that the progress in each step increases the inflating-deflating times according to the adjusted frequency. Due to the overall massage sequence of M4 Overall relaxation mode and Flow cycles are consistent, and the massage pressure range of subject device is within the range of predicate devices, so the small differences do not affect the safety and effectiveness.

The massage sequence of M5 Deep care mode is from the distal end to proximal end, similar to the Wave mode of secondary predicate device. The difference is that the M5 Deep care mode only keeps one chamber in working status at a time, while the Wave mode keeps two chambers in working status at a time. Due to the overall massage sequence of M5 Deep care mode and Wave mode are consistent (From the distal end to proximal end), and the massage pressure range of subject device is within the range of predicate devices, so the small differences do not affect the safety and effectiveness.

9. Conclusions

The subject device has same intended use and similar technological characteristics as the predicate devices. Although there are several specifications that are different between these devices, testing and discussion had 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 conformed with the test requests. Therefore, the differences between the subject device and the predicate devices do not raise any concerns with respect to substantial equivalence. The subject device is substantially equivalent to the predicate devices and the differences in technological characteristics do not raise different questions of safety and effectiveness based on the testing submitted to support this submission.