October 8, 2024

Sichuan QianIi-beoka Medical TechnoIogy lnc.
% Ariel Xiang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K241446
Trade/Device Name: Air Compression Massager (ACM-A1, ACM-A2, ACM-A3, ACM-A4)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 9, 2024
Received: September 9, 2024

Dear Ariel Xiang:

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

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation 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.

510(k) Number *(if known)*
K241446

Device Name
Air Compression Massager (ACM-A1, ACM-A2, ACM-A3, ACM-A4)

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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510(K) Summary

Document Prepared Date: October 4, 2024

A. Applicant:

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B. Subject Device

Device Name: Air Compression Massager
Model(s): ACM-A1, ACM-A2, ACM-A3, ACM-A4
Classification Name: Powered inflatable tube massager
Review Panel: Physical Medicine
Product Code: IRP
Regulation Number: 21 CFR 890.5650
Regulation Class: II

C. Predicate Device

K240122
Normatec Elite
NormaTec Industries, LP

D. Device Description

The Air Compression Massager is a medical device that utilizes the principle of air pressure to provide massage to the legs by inflating and deflating. It aims to provide temporary relief for minor muscle aches or pains while temporarily increasing circulation in treated areas. It consists of a sleeve, a main unit and a battery.

It mimics manual kneading and stroking of tissues through the use of an inflatable pressure sleeve.The sleeve features 5 chambers designed for different body areas including the foot/ankle, calf, knee, lower quad and upper quad. Controlled by the main unit, it can be sequentially inflated and deflated to apply circulating pressure on targeted body areas. The main component materials of the sleeve are Nylon cloth, thermoplastic polyurethane (TPU). It is available in four sizes: XL (Extra large), L (large), M (medium) and S (small).

We offer four models of main unit, ACM-A1, ACM-A2, ACM-A3 and ACM-A4.The main unit is made of polycarbonate (PC) and acrylonitrile-butadiene-styrene (ABS). It is the integrated control center that is responsible for starting and stopping treatments, regulating pressure, and mode selection to ensure a precise and safe treatment process. The user interface is a series of buttons showing battery level, pressure level, mode adjustment. The user interface provides for:

·Starting and stopping the massage treatment;
·Adjusting intensity (pressure) of the treatment;
·Select the treatment mode.

The air compression massager is charged using① an external compliant power supply as well as powered by an internal IEC 62133-2 compliant lithium-ion battery. All four models of the Air Compression Massager are available with 800mAh, 1000mAh and 2000mAh batteries.

In addition, the devices have Bluetooth capability that allows the use of a Mobile 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.

Differences between models:

The ACM-A1, ACM-A3 and ACM-A4 are the same, except for the color of the main unit and the shape of buttons.

The ACM-A2 is different from ACM-A1.Visually, the main unit of ACM-A2 has one more button than the other models. The ACM-A1/3/4 have only one button. The ACM-A2 model

has two buttons, one for the on/off button and the other for the function button.

Model	Main unit(with battery)		Sleeve	Battery
ACM-A1	 800mAh &1000mAh	 2000mAh	 XL (Extra large), L (large), M (medium) S (small).	  800mAh 1000mAh 2000mAh
ACM-A2	 800mAh &1000mAh	 2000mAh		
ACM-A3	 800mAh&1000mAh	 2000mAh		
ACM-A4	 800mAh &1000mAh	 2000mAh		

Specification and Parameters

Characteristic	**ACM-A1/ACM-A3/ACM-A4**	**ACM-A2**
Software / Firmware Micro-processor Control	Microprocessor	
Technology	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	

Pressure range	0-100mmHg	
Pressure Levels	Level 1: 60 mm Hg Level 2: 70 mm Hg Level 3: 80 mm Hg Level 4: 90 mm Hg Level 5: 100 mm Hg	
Treatment Time	Default: 20 min Stays on until the user turns it off or can be set up to turn off in a range of 20 minutes to 60 minutes	
Inflation/Deflation Cycle Type	Sequential Gradient, Peristaltic and Pulsing	
Number of Inflatable segments	5 chambers	
Main Unit Weight	0.4kg	
Main Unit Dimensions (L×W×H)	131mm×65mm×38mm	131mm×65mm×40mm
Product Dimensions (L×W×H)	S: 840mm×330mm × 55mm M: 950mm×380mm × 55mm L: 1020mm×380mm × 55mm XL:1100mm× 410mm ×55mm	S: 840mm×330mm×57mm M: 950mm×380mm×57mm L: 1020mm×380mm×57mm XL:1100mm× 410mm×57mm

Battery	
Input Voltage	DC:5V—2A
Charging Interface	Type-C

Rated Power	25W
Rated Voltage	DC:7.4V
Battery capacity	800mAh 1000mAh 2000mAh
Working Condition	Temperature:5℃∽40℃； Relative Humidity：≤90%； Atmospheric pressure：70kPa∽106kPa
Transport and storage	Temperature:-20℃∽50℃； Relative Humidity：≤90%； Atmospheric pressure：70kPa∽106kPa

The component contacting the user

Model	Component	Contacted Material	Contacted Tissue duration
ACM-A1； ACM-A2； ACM-A3； ACM-A4	Sleeve	1. Inner and Outer cloth of the leg air bag: Nylon cloth, thermopolastic polyurethane (TPU) 2.Zipper: Nylon, metal 3.Edge-wrapping strips: polyester fibre, polypropylene (PP)	Non-conductive wrap Surface Device Intact Skin Long term (＞30day）
	Main unit	Polycarbonate （PC）, Acrylonitrile-butadiene-styrene (ABS)	

E. Indication 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.

F. Comparison to predicate device

Item	Subject device	Predicate device	Discussion
Manufacturer	Sichuan Qianli-beoka Medical Technology Inc.	NormaTec Industries, LP	-
510(K) No.	K241446	K240122	-
Device Name	Air compression Massager Models: ACM-A1, ACM-A2, ACM- A3, ACM-A4	Normatec Elite	-
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	Identical
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	Identical
Regulation Class	Class II	Class II	Identical
OTC& Rx	OTC	OTC	Identical
Indication 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.	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.	Identical
Patient Population	Adults	Adults	Identical

Anatomical Coverage	Main unit mounted to inflatable segment with integral hoses. 	Control unit mounted to inflatable segment with integral hoses. 	Identical
Intended Use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Power source	5 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Integrated rechargeable battery	12 VDC via an IEC 60601-1compliant power supply (100-240 VAC input) Integrated rechargeable battery	Similar
Software/Firmware Micro-processor Control	Microprocessor	Microprocessor	Identical
Technology	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Compressor and valve system that sequentially inflates cells. Bluetooth communication ability.	Identical
Device Pressure Range	0-100mmHg	0 - 110 mm Hg	Similar
Pressure Levels	Level 1: 60 m Hg Level 2: 70 mm Hg Level 3: 80 mm Hg Level 4: 90 mm Hg Level 5: 100 mm Hg	Level 1: 40 mm Hg Level 2: 50 - 60 mm Hg 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	Similar; Tested to meet performance requirements
Treatment Time	Default:20min Stays on until the user turns it off or can be set up to turn off in a range of 20 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	Similar; Tested to meet performance requirements It will not raise any new concerns regarding

			the safety and effectiveness.
Inflation/Deflation Cycle Type	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Identical
Contact Surface Material	Nylon cloth, thermopolastic polyurethane (TPU)	200 denier nylon with a polyurethane laminate/extrusion	Similar; All have been evaluated for biocompatibility according to ISO 10993 and meet the requirements.
Number of Inflatable segments	5 segments for leg attachment	5 segments for leg attachment	Identical
Weight	2.3-2.9 kg (5-6.4 lbs)	3.0 lbs	Similar; Weight and dimensions will not raise any new concerns regarding the safety and effectiveness
Main Unit Dimensions (W×H ×D)	ACM-A1/3/4: 131mm×65mm×38mm(5.16”×2.56”×1.50”) ACM-A2: 131mm×65mm×40mm(5.16”×2.56”×1.57”)	3.5” ×1.75” ×7.0”	

Patient Contact	The contact material meets the requirements of ISO 10993-1	The contact material meets the requirements of ISO 10993-1	Identical

Differences Between Predicate and Subject Device

An “X” indicates the feature is present in the device.

Characteristic	**Subject Device** Air compression Massager Model: ACM-A1,ACM-A2,ACM-A3,ACM-A4	**Predicate Device** Normatec Elite
Power On – The system has settings for:		
Adjustable Treatment time	X	X
Inflatable Leg Boot	X	X
Pressure Levels	5 Pressure Levels	7 Pressure Levels
5 zone Inflatable leg boot	X	X
Time		
User can Add time Before treatment During treatment	X	X
User can Decrease time Before treatment During treatment	X	X
Pressure		
User can Increase level Before treatment During treatment	X	X
User can Decrease level Before treatment During treatment	X	X
Treatment Mode		
Treatment Mode	X	X
Treatment		
Starting via button press	X	X
Pause/Stop via button press	X	X
Un-pause via button press	X	X
End – If timer reaches 0:0000,	X	X

treatment will continue until Rest period is reached.		
Remote operation via Bluetooth app	X	X
Battery Charging		
Main unit interface displays battery level	X	X
main unit interface or battery displays when battery is charging	X	X
Power On/Off Button		
Off mode - No treatment in process	X	X
On mode - Treatment is process when start button also pressed.	X	X
Appliance type		
Selection of appliance – Inflatable boot	X	X

G. Substantial Equivalent discussion

The technology and principle of operation is similar for the proposed device when compared to the predicate device. Both have 5 segments for leg attachment, use the Compressor and valve system that sequentially inflates cells, and have Bluetooth communication ability.

The main unit is mounted to inflatable segment with integral hoses. The treatment time can be controlled, and all three treatment modes are available. Stress can be regulated.

Both are powered by an integrated rechargeable battery, charged via an IEC 60601-1 compliant power supply (100- 240 VAC input).

Differences between Subject and Predicate Device Discussion-

The main differences between the products are dimensions, materials, and main units. The subject device met the requirements of IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. The subject device meets the biocompatibility requirements of ISO 10993-5:2009 & ISO 10993-10:2021 & ISO 10993-23:2021.

Discussion of Differences:

The differences between the subject and predicate device do not raise any new concerns regarding the safety and effectiveness as demonstrated by performance testing.

H. Performance characteristic

The Air Compression Massager has been tested and met the requirements of the following standards:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3: 2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-11:2015+AMD1:2020 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/TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEEE ANSI/USEMCSC C63.27 Wireless Coexistence
- ISO10993-5:2009 Biological evaluations of medical devices -- 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

Additionally, the Air Compression Massager has been tested for the following performance bench testing:

- Pressure accuracy testing
- Seam strength testing to ensure cuffs do not burst if maximum pressure is exceded

Failure mode verification and validation testing to ensure mitigation of overpressurization risk if there is software failure

I. Conclusion

Based on the above data, we can conclude tha[ii]t the subject device Air Compression Massager is as safe and effective as the predicate devices. Thus, the subject device is substantially equivalent to the predicate devices cleared under K240122.