November 23, 2021

Foshan Hongfeng Co., Ltd.
℅ Sam Lin
Official Correspondent
Shanghai Spica Management Consulting Co., Ltd.
609 Room, No.133 Shengang Avenue, Pudong New District
Shanghai, 201306 Cn

Re: K212169
Trade/Device Name: Air compression therapy system FO3002
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: October 18, 2021
Received: October 18, 2021

Dear Sam Lin:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212169

Device Name
Air compression therapy system FO3002

Indications for Use *(Describe)*
Air compression therapy system FO3002 is intended for home 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary

K212169

Type of Submission Traditional

Date Prepared May 31, 2021

Submission Sponsor

Manufacturer Name	FOSHAN HONGFENG CO., LTD.
Address	No.4-2 Leqiang Road, Leping Sanshui, Foshan, Guangdong, China
Tel	86-0757-8392028
Email	573619164@qq.com
Contact Person	Dongfeng Cheng

Device Identification

Trade Name	Air compression therapy system FO3002
Regulation Number	21 CFR 890.5650
Regulation Name	Power inflatable tube massager
Device Classification	Class II
Product Code	IRP
Panel	Physical Medicine
Previous Submissions	**None**

Application Correspondent

Company Name	Shanghai Spica Management Consulting Co., Ltd.
Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China
Tel	86-15626132181
Email	sam@spicagloble.com
Contact Person	Sam Lin

Indications for Use

Air compression therapy system FO3002 is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

Device Description

Air compression therapy system FO3002 is consist of air pressure sensor, air pump, sleeves etc

working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses. 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 sensor and microprocessor.
Air compression therapy system FO3002, in medical market, it has a sequential squeezing from distal to proximal, thus help to improve circulation to the treated areas. Clothing should be worn between the device and the patient's skin.

Predicate and Reference Device Information

Sponsor	NormaTec Industries, LP
Trade/Device Name	NormaTec Pulse and NormaTec Pulse Pro
510(K) number	K160608
Regulation Number	21 CFR 890.5650

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

Not Applicable.

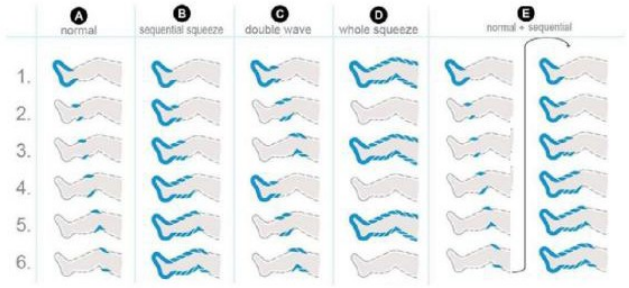
Table 6A: Summary of Comparison

	Subject Device	Predicate Device	Differences Discussion
Device name	Air compression therapy system FO3002	NormaTec Pulse and NormaTec Pulse Pro	N/A
510(k) number	K212169	K160608	N/A
Manufacturer	FOSHAN HONGFENG CO., LTD.	NormaTec Industries, LP	N/A
Product regulation	21 CFR 890.5650	21 CFR 890.5650	Same
Classification name	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube	Same
Regulation class	2	2	Same
Product code	IRP	IRP	Same
Indications for use	Air compression therapy system FO3002 is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	Same
Rx or OTC	OTC	OTC	Same
Pressure range	30-110mmHg	30-110mmHg	Same
Treatment time	10-60min	Stays on until the user turns it off or can be set up to turn off in a range of 10 mins to	Similar The treatment time of subject device is smaller than predicate

		continuous / User controlled 10 minutes to 175 minutes or continuous –total time over 4 segments.	device (K160608), so the difference of treatment time would not raise adversely impact on safety and effectiveness.
Standard	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, IEC 60601-1-2, IEC 60601-1-11 , IEC 62133-2, ISO 10993-5, ISO 10993-10	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Similar
Mode of compression	Sequential	Sequential Gradient, Peristaltic and Pulsing	Same
Power source	Adaptor: AC 100-240V, 50/60Hz Main unit: DC 15V, 1.5A	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Optional Integrated rechargeable battery	Similar
Power consumption	22.5VA	14W	Similar
Dimensions (W*H*D)	265 x 130 x 100mm	4” x 5” x 9”	Similar
Photo		N/A	N/A
Size and appearance of sleeves (leg part)		Short: 14” x 43” Standard: 14” x 48” Tall: 14” x 60”	Similar

	XL: 110 x 70cm XXXL: 125 x 76cm		
Housing materials	Molded ABS enclosure	Molded ABS enclosure	Same
Number of chambers	6	5 or less	Similar
Work mode	A Normal Mode: Chamber ① inflates to pressure set value within maximum 12 seconds. If the chamber pressure reaches preset value within 12 seconds, holding pressure on for the rest of the period then shift to next chamber inflating. If the chamber pressure doesn't reach pressure preset value within the first 12 seconds, inflation is extended for additional maximum 10 seconds. Within this 10-second period, if the chamber pressure reaches the preset value, then shift to next chamber inflating. If the chamber pressure cannot reach the preset value at the end of additional 10 seconds, then shift to next chamber inflating automatically. 3 seconds after the next chamber (for example Chamber ②) inflating, the inflated chamber (for example Chamber ①) deflates. Chamber ② works like Chamber ①. Chamber ③, ④, ⑤, ⑥ repeats the similar procedure as Chamber ②, ③, ④, ⑤. B Sequential Mode: Chamber ① inflates to pressure set value within maximum 12 seconds. If the chamber pressure reaches preset value within the 12 seconds, holding pressure on them shift to next chamber inflating. If the chamber pressure doesn't reach pressure preset value within the first 12 seconds, inflation is extended for additional maximum 10 seconds. Within this	Sequential mode: Starting with the distal chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the top section decompresses, the cycle begins again. again. Normatec Pulse mode: Starting with the distal zone and progressing up the proximal zone, one zone compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air of previous two zone, the other zones do not hold, until the last zone	Although the subject device provides 5 kinds of work mode, the Mode A and Mode C are the same with predicate device (K160608), while the other work modes of subject device just have difference about inflatable order of the different chambers. The treatment pressure range are the same under different work modes, so the difference of pressure range would not raise adversely impact on safety and effectiveness.

	10-second period, if the chamber pressure reaches the preset value, holding pressure on then shift to next chamber inflating. If the chamber pressure cannot reach the preset value at the end of additional 10 seconds, holding pressure on then shift to next chamber inflating automatically. Chamber ② works like Chamber ①. Chamber ③, ④, ⑤, ⑥ repeats the similar procedure as Chamber ②, ③, ④, ⑤. After the last Chamber ⑥ completed inflation, Chamber ①, ②, ③, ④, ⑤, ⑥ operation cycle starts 13 seconds after deflation begins. C Double Mode: Chamber ① ② as a group inflates synchronously to pressure set value within maximum 24 seconds. If the grouped chamber pressure reaches preset value within the 24 seconds, holding pressure on for the rest of the period then shift to next group (③ ④) inflating. If the grouped chamber pressure doesn't reach pressure preset value within the first 24 seconds, inflation is extended for additional maximum 20 seconds. Within this 20-second period, if the Chamber ① ② pressure reaches the preset value, then shift to next group (③ ④) inflating. If the Chamber ① ② pressure cannot reach the preset value at the end of additional 20 seconds, then shift to next group (③ ④) inflating automatically. 3 seconds after the next group (Chamber ③ ④) inflating, the inflated group (Chamber ① ②) deflates. Chamber group ③ ④/⑤ ⑥ works like Group ① ②. Start next Chamber (① ②)-(③ ④)-(⑤ ⑥) operation cycle 13 seconds after Chamber group ⑤ ⑥ begins deflation. D Whole Mode: Chamber ①, ②, ③, ④, ⑤, ⑥ inflates synchronously to pressure set value within maximum 72 seconds.	finished, deflate the all last three zone then enter into next cycle.	

	If the chamber pressure reaches preset value within the 72 seconds, holding pressure on for the rest of the period, then deflates synchronously. If the chamber pressure doesn't reach pressure preset value within the first 72 seconds, inflation is extended for additional maximum 36 seconds. Within this 36-second period, if the chamber pressure reaches the preset value, then deflates synchronously. If the chamber pressure cannot reaches the preset value at the end of additional 36 seconds, then Chamber ①, ②, ③, ④, ⑤, ⑥ deflates automatically. Repeat the Chamber ①, ②, ③, ④, ⑤, ⑥ operation cycle 13 seconds after Chamber ①, ②, ③, ④, ⑤, ⑥ deflation begins. E Combined A mode + B mode: Normal Mode followed by Sequential Mode 		
Safety feature	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	Same
Technology	Compressor and valve system which sequentially inflates inflatable chambers	Compressor and valve system which sequentially inflates	Same

		inflatable chambers	

Performance Characteristic

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 - 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
ISO 10993-5: 2009 - Biological Evaluation of Medical Device - Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10: 2010 - Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization
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

Conclusion

Based on the indications for use, technological characteristics, and non-clinical performance data, “Air compression therapy system FO3002 (K number)” is as safe, as effective, and performs as well as the legally marketed predicate devices, “NormaTec Pulse and NormaTec Pulse Pro (K160608)”. Therefore, the subject device is substantially equivalent to the predicate device.