March 25, 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
China

Re: K201982
Trade/Device Name: Air compression therapy system FO-3001; Air compression therapy system FO-3008
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: July 17, 2020
Received: July 17, 2020

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,

Jitendra Virani
Acting Assistant Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201982

Device Name
Air compression therapy system FO-3001;
Air compression therapy system FO-3008

Indications for Use *(Describe)*
Air compression therapy system Models FO-3001 and FO-3008: Intended for home to temporarily relieve minor muscle aches and/or pains, promote blood circulation in 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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K201982: 510(k) Summary

Type of Submission Traditional

Date Prepared February 4, 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 FO-3001; Air compression therapy system FO-3008
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 of the Device

Air compression therapy system Models FO-3001 and FO-3008: Intended for home to temporarily relieve minor muscle aches and/or pains, promote blood circulation in the treated areas.

Device Description

Air compression therapy system Models FO-3001 and FO-3008: Air Pressure Therapy System 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 Pressure Therapy System, in medical market, it has a sequential squeezing from distal to proximal, thus help to improve the circulation of blood.

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

Not Applicable.

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Table 6A: Predicate Device Information

No.	Regulation Number	510k Number	Sponsor	Predicate Device Name	Rx or OTC	Treatment Time	Pressure Range
1	21 CFR 890.5650	K160608	NormaTec Industries, LP	NormaTec Pulse and NormaTec Pulse Pro	OTC	Stays on until the user turns it off or can be set up to turn off in a range of 10 mins to continuous / User controlled 10 minutes to 175 minutes or continuous – total time over 4 segments	30-110mmHg

Table 6B: Differences between Models

Note：* "×" means same.

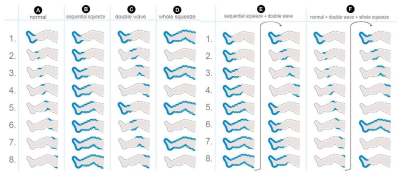
Characteristic	Air Compression Therapy System: FO-3001	Air Compression Therapy System: FO-3008
Indications for use	×	×
OTC	×	×
Device Pressure Range	×	×
Treatment Time	×	×
Standard	×	×
Mode of Compression	×	×
Power Source	×	×
Power Consumption	×	×
Size and appearance of sleeves	×	×
Housing Materials	×	×

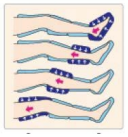
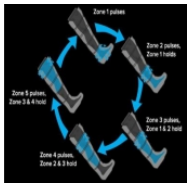
Safety Feature	×	×
Technology	×	×
Dimensions	Different, see the Table 6C for details	Different, see the Table 6D for details
Photo	Different, see the Table 6C for details	Different, see the Table 6D for details
Number of Chambers	Different, see the Table 6C for details	Different, see the Table 6D for details
Work Mode	Different, see the Table 6C for details	Different, see the Table 6D for details

Table 6C: Summary of Comparison of FO-3001

	Subject Device	Predicate Device	Differences Discussion
Device Name	Air compression therapy system: FO-3001	NormaTec Pulse and NormaTec Pulse Pro	N/A
510(k) number		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	Intended for home to temporarily relieve minor muscle aches and/or pains, promote blood circulation in 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	1-60mins	Stays on until the user turns it off or can be set up to turn off in a range of 10 mins to continuous / User controlled 10 minutes to 175 minutes or continuous –total time over 4 segments.	Similar The treatment time of subject device is smaller than predicate device (K160608), so the difference of treatment time would not raise adversely impact on safety and effectiveness.
Standard	IEC 60601-1-11:2015 IEC 60601-1-2:2014 IEC 60601-1:2005 ISO 10993-10:2010 ISO 10993-5:2009 ISO 10993-12:2012	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Similar
Mode of Compression	Sequential	Sequential Gradient, Peristaltic and Pulsing	Same
Power Source	100-127V/220-240V, 50/60Hz	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input)	Similar

		Optional Integrated rechargeable battery	
Power Consumption	65W	14W	Similar
Dimensions (W*H*D)	220*190*113MM	4” x 5” x 9”	Similar
Photo			Similar
Size and appearance of sleeves (leg part)	 M:91*65cm L:100*74cm XL:110*70cm (Overlapping)	 Short: 14” x 43” Standard: 14” x 48” Tall: 14” x 60”	Similar
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Same
Number of Chambers	4,6,8 Chambers for each unit	5 or less	Similar
Work Mode		Sequential mode: Starting with the distal chamber and progressing up the proximal chamber, each section compresses and the pressure gradually rises to the	Although the subject device provides six kinds of work mode, the Mode A is the same with predicate device (K160608), while the other work modes of subject device just have difference about the

	6 chambers: A (Normal Mode): Chamber ① inflating till setup pressure or for 2 seconds, then hold air for 2 seconds, start deflating; chamber ② start like ①. Same way till chamber ⑥, pause for 3 seconds, then restart chamber ①②③④⑤⑥ again. B (Sequential Squeeze Mode): chamber ① inflating till set up pressure or for 28 seconds, then hold the pressure, chamber ② inflating, till setup pressure or for 28 seconds, then chamber ①② hold pressure in same time, then chamber ③ start inflating, same way till after chamber ⑥. Chamber ①②③④⑤⑥ deflating in same time for 3 seconds. Then repeat. C (Double Wave Mode: chamber ①② inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then start deflating. Chamber ③④ start inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then deflating, same way for chamber ③④ till chamber ⑤⑥, pause for 3 seconds. Then repeat. D (Whole Squeeze Mode): chamber ①②③④⑤⑥ inflating at the same time till setup pressure or for 90 seconds, then deflating in the same time for 3 seconds. Then	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 finished, deflate the all last three zone then enter into next cycle. 	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.

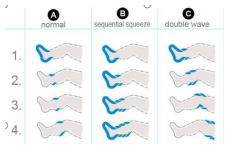
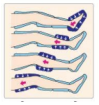
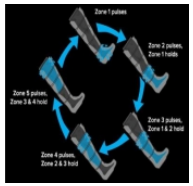
	repeat. E (Combined B + C): sequential squeeze + double wave F (Combined A + C + D): normal + double wave + whole squeeze. 4 and 8 chambers same as 6 chambers above.		
Safety feature	Power button on main unit allows user to stop therapy session at any time	Button on display allows user to stop or pause therapy session at any time	Same
Technology	Compressor and valve system which sequentially inflates inflatable chambers	Compressor and valve system which sequentially inflates inflatable chambers	Same

Table 6D: Summary of Comparison of FO-3008

	Subject Device	Predicate Device	Differences Discussion
Device Name	Air compression therapy system: FO-3008	NormaTec Pulse and NormaTec Pulse Pro	N/A
510(k) number		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	Intended for home to temporarily relieve minor muscle aches and/or pains, promote blood circulation in 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	1-60mins	Stays on until the user turns it off or can be set up to turn off in a range of 10 mins to continuous / User controlled 10 minutes to 175 minutes or continuous –total time over 4 segments.	Similar The treatment time of subject device is smaller than predicate device (K160608), so the difference of treatment time would not raise adversely impact on safety and effectiveness.
Standard	IEC 60601-1-11:2015 IEC 60601-1-2:2014 IEC 60601-1:2005 ISO 10993-10:2010 ISO 10993-5:2009	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	Similar

	ISO 10993-12:2012		
Mode of Compression	Sequential	Sequential Gradient, Peristaltic and Pulsing	Same
Power Source	100-127V/220-240V, 50/60Hz	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Optional Integrated rechargeable battery	Similar
Power Consumption	65W	14W	Similar
Dimensions (W*H*D)	240*200*110MM	4” x 5” x 9”	Similar
Photo			Similar
Size and appearance of sleeves (leg part)	 M:91*65cm L:100*74cm XL:110*70cm (Overlapping)	 Short: 14” x 43” Standard: 14” x 48” Tall: 14” x 60”	Similar
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Same

Number of Chambers	4 Chambers for each unit	5 or less	Similar
Work Mode	 A (Normal Mode): Chamber ① inflating till setup pressure or for 2 seconds, then hold air for 2 seconds, start deflating; chamber ② start like ①. Same way till chamber ④, pause for 3 seconds, then restart chamber ①②③④ again. B (Sequential Squeeze Mode): chamber ① inflating till set up pressure or for 28 seconds, then hold the pressure, chamber ② inflating, till setup pressure or for 28 seconds, then chamber ①② hold pressure in same time, then chamber ③ start inflating, same way till after chamber ④. Chamber ①②③④ deflating in same time for 3 seconds. Then repeat. C (Double Wave Mode: chamber ①② inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then start deflating. Chamber ③④ start inflating till setup pressure or for 40 seconds, hold air for 2 seconds, then deflating.	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 finished, deflate the all last three zone then enter into next cycle. 	Although the subject device provides four kinds of work mode, the Mode A is the same with predicate device (K160608), while the other work modes of proposed device just have difference about the 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.

Safety feature	Power button on main unit allows user to stop 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 inflatable chambers	Same

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 1-1: 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: 2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 - Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- ISO 10993-10: 2010 - Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization, an assessment is made of the potential of the material under test to produce dermal irritation in a relevant animal model
- ISO 10993-5:2009 - Biological Evaluation of Medical Device - Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-12:2012 - Biological Evaluation of Medical Device - Part 12: Sample preparation and reference materials

Conclusion

Based on the indications for use, technological characteristics, and non-clinical performance data, Air compression therapy system Models FO-3001 and FO-3008 (510(K) number) is as safe and effective as the legally marketed predicate devices, NormaTec Pulse and NormaTec Pulse Pro(K160608).