April 23, 2020

Xiamen Senyang Co., Ltd.
℅ Raymond Luo
Technical Manager
Shanghai SUNGO Management Consulting Co., Ltd.
13th F, 1500# Century Avenue
Shanghai, China 200122

Re: K192358
Trade/Device Name: Pressure Therapy System PT1003
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 12, 2019
Received: February 26, 2020

Dear Raymond Luo:

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 Vivek J. Pinto, PhD
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192358

Device Name
Pressure Therapy System PT1003

Indications for Use *(Describe)*
The device is 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

A. Applicant:

Name: XIAMEN SENYANG CO., LTD.
Address: 4-5 FLOOR, XINGBEI INDUSTRY, NO 95-99, WEST 2 ROAD, JIU TIANHU, XINGLIN XIAMEN, 361000, P.R. China

Official Contact Person Information
Shanghai SUNGO Management Consulting Co., Ltd.
Name: Raymond Luo
Tel: 0086-21-68828050
Mail: fda.sungo@gmail.com

B. Subject device:

Trade name:	Pressure Therapy System PT1003
Common name:	Powered inflatable Tube Massager
Classification name:	Massager, Powered Inflatable Tube
Regulation Medical Specialty	Physical Medicine
Regulation Number	890.5650
Product Code	IRP
Classification	Class II

C. Predicate device:

01. Pulse 2.0, Pulse Pro 2.0 of NormaTec Industries, LP, K183169
02. Rapid Reboot Compression Therapy System, Rapid Reboot Recovery Products, LLC, K182668

D. Reference device:

K181409, Pressure Therapy System PT1003, Rx Only

E. Indications for Use:

The device is air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

F. Prescriptive

The Pressure Therapy System PT1003, and the predicate (K183169 and K182668) are OTC devices.

G. Device Description:

The system consists of an air pump, leg sleeves and hoses working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses; one sleeve has 4 compression chambers. 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. This software is to control the timing and the pressure reflected by the sensor, it cycles the airflow to reach the function of cycling compression of body parts.

H. Substantial Equivalence Table

Device	Subject Device	Predicate Device 01	Predicate Device 02
Manufacturer	XIAMEN SENYANG CO., LTD.	NormaTec Industries, LP,	Rapid Reboot Recovery Products, LLC
Model Name	Pt 1003	Pulse 2.0, Pulse Pro 2.0	Not Publicly Available
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)
Prescriptive	No. OTC	No. OTC	No. OTC
Indications for use	The device is air pressure massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The device is air pressure massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The Rapid Reboot Compression Therapy System 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 Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.
Intended use Environment	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments
Standard	AAMI ANSI ES 60601-1:2005/(R)2012 and A1:2012 IEC 60601-1-11. IEC 60601-1-2 ISO10993-5& ISO10993-10	AAMI ANSI ES 60601-1:2005/(R)2012 and A1:2012 IEC 60601-1-11. IEC 60601-1-2 ISO10993-5& ISO10993-10	IEC 60601-1:2014; IEC 60601-1-2:2014; EN ISO 10993-5:2009 & EN ISO 10993-10:2010
Software Micro-processor Control	Microprocessor	Microprocessor	Microprocessor
Mode of Compression	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing	Sequential Gradient, Peristaltic and Pulsing
Power Source	110 V, 60Hz	15 VDC via an IEC 60601-1 compliant power supply (100- 240 VAC	110 V, 60Hz

		input) Integrated rechargeable battery	
Therapy Time	0-30Min	Stays on until the user turns it off or can be set up to turn off in a range of 10 minutes to continuous.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.
Max Pressure Min Pressure	20-200mm Hg	0-110mm Hg	0-200 mmHg
Number of Chambers	4 Chambers for each unit	5 or less	4 Chambers for each unit
Compression Applicator Garments Sleeve Material	Thermoplastic Urethane	200 denier nylon with a polyurethane laminate/extrusion	Nylon with a Polyurethane laminate
Technology	Compressor and valve system that sequentially inflates cells of appliance.	Compressor and valve system that sequentially inflates cells of appliance.	Compressor and valve system which sequentially inflates cells of appliance
Cycle time	70s	Not Publicly Available	1 min 20s
Patient Contact	Non-conductive appliances	Non-conductive appliances	Non-conductive appliances
Size	Size 285*175*130mm	Size: 4.4” x 3.8” x 8.1”	Size: 10” x 6.5” x 5”
Preprogrammed modes	Model Adjustable: The number of zones that are enabled in the attachment can be changed between one and five zones.	Model Adjustable: The number of zones that are enabled in the attachment can be changed between one and five zones.	2 modes: "A" mode inflates and deflates chambers from bottom up (distal to proximal chambers), one at a time. "B" mode also inflates chambers from bottom up, but maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated.

I. Determination of Substantial Equivalence

The following factors of Pressure Therapy System PT1003 are substantially equivalent to currently marketed and cleared devices (K183169).

- Indications for Use: The Pressure Therapy System PT1003 indications for use are identical to the predicate, NormaTec Pulse 2.0, Pulse Pro 2.0, 510(k) K183169.
- Prescriptive: The Pressure Therapy System PT1003, and the predicate (K183169) are OTC devices.
- Performance and Specifications: The Pressure Therapy System PT1003 have equivalent specifications of performance when compared to the predicate, NormaTec Pulse 2.0, Pulse Pro 2.0, 510(k) K183169.
- Compliance with Standards: Both subject device and predicate device comply with the same standards expect the special standard related to the blue tooth function.
- Intended Use Environment: Clinics, hospital, athlete training, and home environments, which are identical to the predicate.
- Materials for patient contact are Non-conductive appliances.

The following factors of Pressure Therapy System PT1003 are different from currently marketed and cleared devices (K183169).

- Pressure range of the predicate device is 0-110mm Hg while current device is 20-200mm Hg. To ensure the pressure is safe, we identified another predicate device, K182668, which is also for OTC use and the pressure scope is 0 to 200mmHg.
- Design, Technology, and Principle of Operation: The proposed device has not got Bluetooth capability but this will not bring any new risk to the subjected device.

J. Performance characteristic

The Pt1003 pressure therapy system has been tested and met the requirements of the following standards:
AAMI ANSI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
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 Edition 2.0 2015-01, 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
ISO10993-5, Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Function test

- Minimum and maximum air pressure test
- Test the maximum electric current value
- Test the maximum airflow value
- Test the noise level
- Test the modes A and B.

The test was done on PT1003 following the test procedure defined. When we compare the test data with the predicate device, we can found the test result is almost same.

K. Conclusion

The Pt1003 Pressure Therapy System has substantially equivalent intended use as the cleared NormaTec Pulse 2.0, Pulse Pro 2.0, (K183169) and has substantially equivalent technological and performance characteristics. The pressure scope is safe by compare with the predicate device Rapid Reboot Recovery Products, LLC, K182668. After analyzing laboratory testing to applicable standards, it is concluded that Pt1003 Pressure Therapy System is as safe and effective as the predicate device, has few technological differences, but there are no new indications for use and does not raise any new safety and/or effectiveness concerns. Consequently, it is substantially equivalent to the predicate device.