DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 22, 2017

Xiamen Senyang Co., Ltd.
% Raymond Luo
Technical Manager
Shanghai SUNGO Management Consulting Company Limited
4th Floor 1500# Central Avenue
Shanghai, Shanghai 200122 CN

Re: K161907
Trade/Device Name: Pressure Therapy System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 26, 2017
Received: January 26, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K161907

Device Name
Pressure Therapy System

Indications for Use *(Describe)*
The device is indicated for use by medical professionals and patient at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injuries, post immobilization edema, venous insufficiencies, lymphedema.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

K161907

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
Name: Raymond Luo
Tel: 0086-21-68828050
Mail: fda.sungo@gmail.com

B. Subject device:

Trade name:	Pressure Therapy System
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:

K113275 - Compressible Limb Therapy System (Power-Q1000 Premium)

D. Indications for Use:

The device is indicated for use by medical professionals and patient at home, who are under medical supervision, in treating many conditions, such as: Primary lymph edema, edema following trauma and sport injures, Post immobilization edema, Venous insufficiencies, Lymph edema.

E. 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.

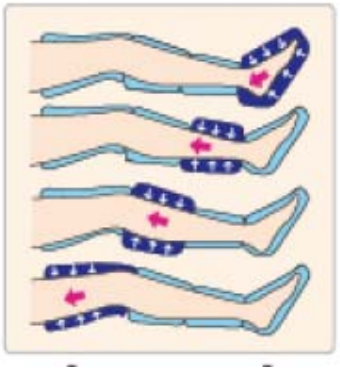
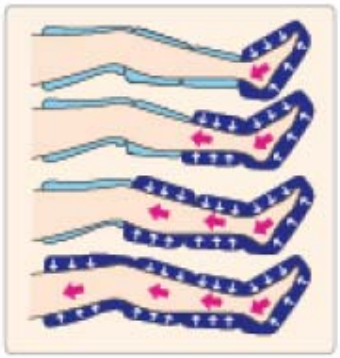
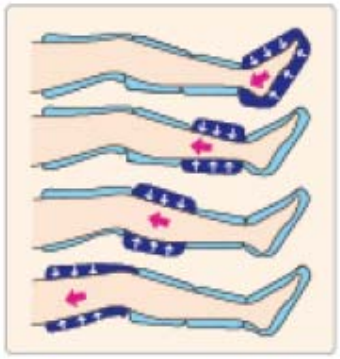
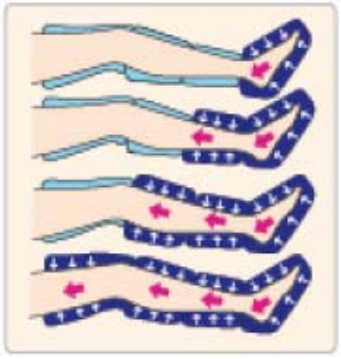
F. Technical Characteristic:

Name	Pt 1002

Pressure (mmHg)	0~250 mmHg
Mode	Mode A and Mode B selection and the initial is A
Cycle time	30s
Pressure Time	Time 0-30 min, selection (10, 20, 30min)

G. Substantial Equivalence Table:

Device	**Subject Device (K161907)**	**Predicate Device (K113275)**
Manufacturer	XIAMEN SENYANG CO., LTD.	BSR KOREA Corp.
Model Name	Pt 1002	Power Q1000 Premium
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)
Indications for Use	The device is indicated for use by medical professionals and patient at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injures, Post-immobilization edema, Venous insufficiencies, Lymphedema.	The device is indicated for use by medical professionals and patient at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injures, Post-immobilization edema, Venous insufficiencies, Lymphedema.
Description	Pt 1002 is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.	Power Q1000 Premium is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.
Standard	IEC 60601-1 & IEC 60601-1-2 ISO10993-5 & ISO10993-10	EN 60601-1& EN 60601-1-2
Indications	Primary lymphedema, edema following trauma and sport injures, Post-immobilization edema, Venous insufficiencies, Lymphedema	Primary lymphedema, edema following trauma and sport injures, Post-immobilization edema, Venous insufficiencies, Lymphedema
Mode of Compression	Sequential	Sequential
Power Source	110 V, 60Hz	110V, 60Hz
Therapy Time	0 – 30 mins	0 – 99 mins
Max Pressure Min Pressure	0-250mm Hg	0-240mm Hg
Number of Chambers	4 Chambers for each unit	4 Chambers for each unit
Compression Applicator Garments Sleeve Material	Thermoplastic Urethane	Nylon
Power	30W	30W

consumption		
Cycle time	30s	0, 5, 10, 15, 20, 25, 30s selection Initial is 0s
Size	Size 260*170*130mm 	Size:150*210*210mm 
Body area specific cuffs	Small Leg Cuff LXW:90X30cm Large Leg Cuff LXW:110X30cm 	Leg: 
Preprogrammed modes	Model A  Model B 	Model A  Model C 

From the comparison in the form above, the intended use, indication for use and the Mode of Compression, Power Source, Power consumption of the two devices are same. There are some factors that are different:

1) Biocompatibility: The subject device has different sleeve material than the predicate device but subject device complies to ISO 10993-5 and ISO 10993-10 standards.

2) Therapy Time: For one time use, the max time for this device is 30 min. This is safer than the predicate device's max time of 90 min. If the user wants, he/she can repeat the 30 min cycle.

3) Min Pressure and Max Pressure: The Max pressure of the subject device is 250 mmHg which is similar to the max pressure of 240mm Hg in the predicate device.

4) Preprogrammed modes: The subject device only has 2 selections which are within the scope of the predicate device. Model A of the subject device is identical to Model A of the predicate device. Model B of the subject device is identical to Model C of the predicate device.

H. Performance characteristic

The Pt1002 pressure therapy system has been tested and met the requirements of the following standards:

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

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

I. Conclusion

The Pt1002 Pressure Therapy System has substantially equivalent intended use as the cleared Power Q1000 Premium Compression Limb Therapy System and has substantially equivalent technological and performance characteristics. After analyzing laboratory testing to applicable standards, it is concluded that Pt1002 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.