February 19, 2019

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

Re: K181409
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: December 19, 2018
Received: December 21, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -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)*
K181409

Device Name
Pressure Therapy System PT1003

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 lymph edema, edema following trauma and sport injuries, Post immobilization edema, Venous insufficiencies, Lymph edema.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
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:

K161907 Pressure Therapy System PT1002 produced by XIAMEN SENYANG CO., LTD.

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.

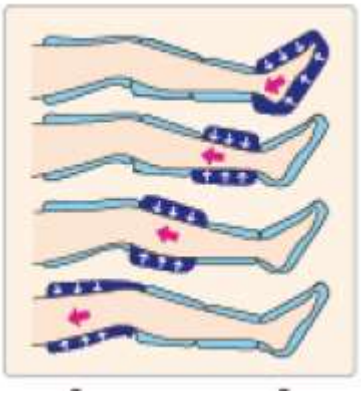
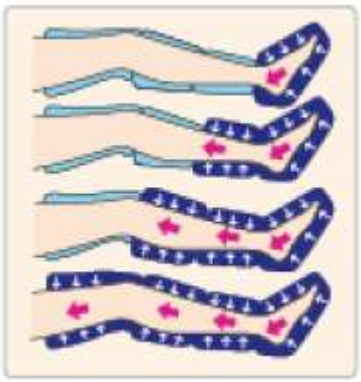
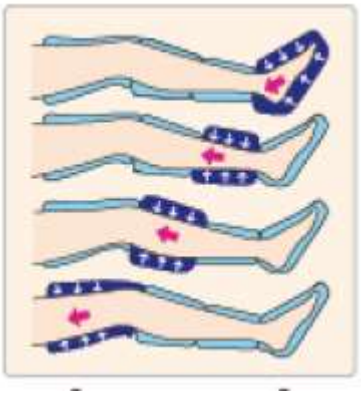
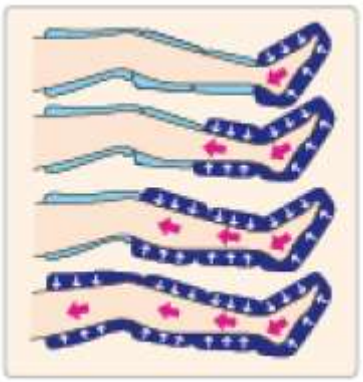
F. Technical Characteristic:

Name	**Pt 1003**
Pressure (mmHg)	0~250 mmHg
Mode	Mode A and Mode B selection and the initial is A
Interval	50s

Time(min)	Time 0-30, selection (10, 20, 30min)
Pressure Time	Pressure, 20-250mmHg, Mode A/B, 0-30Min

G. Substantial Equivalence Table:

Device	**Subject Device**	**Predicate Device**
Manufacturer	XIAMEN SENYANG CO., LTD.	XIAMEN SENYANG CO., LTD.
Model Name	Pt 1003	Pt 1002
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)
Intend 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 1003 is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.	Pt 1002 is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.
Standard	AAMI ANSI ES 60601-1:2005/(R)2012 and A1:2012 IEC 60601-1-2 ISO10993-5& ISO10993-10	AAMI ANSI ES 60601-1:2005/(R)2012 and A1:2012 IEC 60601-1-2 ISO10993-5& ISO10993-10
Indications	Primary lymphedema, edema following trauma and sport injures, Postimmobilization edema, Venous insufficiencies, Lymphedema.	Primary lymphedema, edema following trauma and sport injures, Postimmobilization edema, Venous insufficiencies, Lymphedema.
Mode of Compression	Sequential	Sequential
Power Source	110 V, 60Hz	110 V, 60Hz
Therapy Time	0-30Min	0-30Min
Max Pressure Min Pressure	0-250mm Hg	0-250mm Hg
Number of Chambers	4 Chambers for each unit	4 Chambers for each unit
Compression Applicator Garments Sleeve Material	Thermoplastic Urethane	Thermoplastic Urethane
Power	30W	30W

consumption		
Cycle time	30s	30s
Size	Size 260*170*130mm 	Size: 260*170*130mm 
Body area specific cuffs	Small Leg Cuff LXW:90X30cm Large Leg Cuff LXW:110X30cm 	Small Leg Cuff LXW:90X30cm Large Leg Cuff LXW:110X30cm 
Preprogrammed modes	Model A  Model B 	Model A  Model B 

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. Also the Leg cuff material which may contact with the user is same as the predicate device. There are some factors are different.

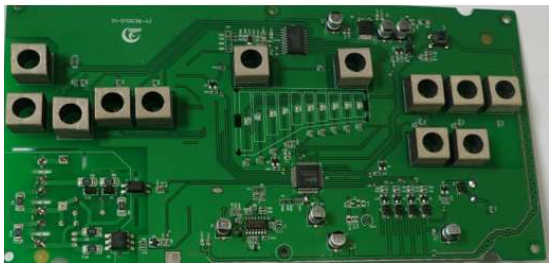
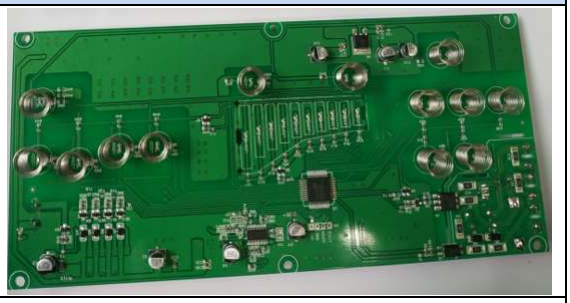
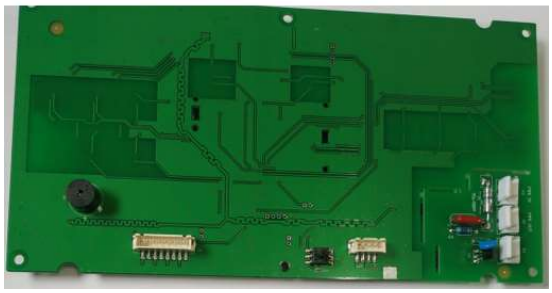
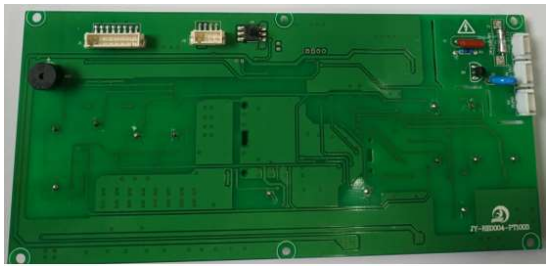
1) Appearance of the product was changed, which has not brought any new risk or concerns.

Item	**Subject Device**	**Predicate Device**
Size	260*170*130mm	260*170*130mm
Appearance		

The difference of the appearance did not change any safety and performance of the device, which is just updated to meet the customer's expectation.

2) PCB of the product has been changed.

The actual change of the PCB may be found in the form below.

Item	**Predicate Device**	**Subject Device**
PCB Front Side Layout		
PCB Back Side Layout		
Main Micro Processor	Type： EM78F668N Pack： 44pin-QFP	Type： BS66F350 Pack： 44 LQFP-A
Touch Micro Processor	Type： BS83B12A-3 Pack： 20 SOP-A	No use
Touch key	Sponge	Spring

Regarding the safety aspect, the microprocessor of subject device, EM78F668N has the same work temperature

and the fire-protection rating as the microprocessor of the predicate device. Regarding the performance aspect, through appropriate software, the subject device has the same air flow rate, pressure and time setting with the predicate device.

According to the analysis above, we find the difference between the subject device and the predicate device will not affect the safety or performance of the subject device.

H. 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

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.

I. Conclusion

The Pt1003 Pressure Therapy System has substantially equivalent intended use as the cleared Pt1002 Pressure Therapy System and has substantially equivalent technological and performance characteristics. 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.