February 19, 2022

Xiamen Simo Electronic Co., Ltd
℅ Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North RD.
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Beijing, Beijing 102401
China

Re: K212935
Trade/Device Name: Air Pressure Foot Massager
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: December 24, 2021
Received: December 27, 2021

Dear Ray Wang:

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,

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)*
K212935

Device Name
Air Pressure Foot Massager

Indications for Use *(Describe)*
Air Pressure Foot Massager is 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.

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

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510(k) Summary

The assigned 510(k) Number: K212935

1. Date of Preparation

   02/05/2022

2. Sponsor

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4. Identification of Proposed Device

Trade Name: Air Pressure Foot Massager
Common Name: Physical Medicine
Model(s): SM-512F

Regulatory Information:
Classification Name: Massager, Powered Inflatable Tube
Classification: II;
Product Code: IRP;
Regulation Number: 21 CFR 890.5650；
Review Panel: Physical Medicine.

Indication for Use:
Air Pressure Foot Massager is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.

5. Device Description

Air Pressure Foot Massager has a pump. The pump is connected with the dedicated inflatable sleeve through the hose, one sleeve has 2 compression chambers. The pump compresses and inflates air into the chambers continuously to produce compression from the body tail end to body center and release the air after compression as one cycle process.

The device is equipped with a hand controller. In operation, the user simply turns the power on via the power button. The intensity (pressure) can be adjusted by purpose to avoid any discomfort. The device is powered by an external IEC 60601-1 compliant power supply and can also be powered by an internal IEC 62133-compliant lithium-ion battery. The materials of sleeve use medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.

The Air Pressure Foot Massager is a portable and rechargeable device. It is intended to be an over-the-counter portable inflatable tube massage system which simulates kneading and stroking of tissue by use of an inflatable sleeve. It can be used to temporarily increase blood circulation and temporarily relieve minor muscle aches and pains.

6. Identification of Predicate Device

Predicate Device
510(k) Number: K201935
Product Name: Air Pressure Therapy System
Manufacturer: Xiamen Weiyou Intelligent Technology Co., Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI ES60601-1:2005+A1:2012, Medical Electrical Equipment - Part 1: General Requirements for Safety And Essential Performance (IEC 60601-1);
- 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-Requirements and tests.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for 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.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device（K201935）	Remark
Product Code	IRP	IRP	SAME
Regulation No.	21 CFR 890.5650	21 CFR 890.5650	SAME
Class	II	II	SAME
Indication For Use	Air Pressure Foot Massager is intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	Air Pressure Therapy System VU-IPC04B is 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
Technology	Compressor and valve system which sequentially inflates inflatable chambers.	Compressor and valve system which sequentially inflates inflatable chambers.	SAME

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device（K201935）	Remark
Pressure range	30-110mmHg	30-110mmHg	SAME
Treatment time	0-30min, default as 15min	5-99mins	Analysis 1
Mode of compression	Sequential	Sequential	SAME
Power source	Voltage: DC5V 1A Lithium Battery: 3.7V, 2400mah (Battery meet IEC 62133-2)	AC 110-240V; 50Hz/60Hz Battery meet IEC 62133-2	Analysis 2
Power consumption	5W	35W	Analysis 2
Number of chambers	4pcs/Pair	6	Analysis 3
Size of the sleeves	340*365*360mm	M: 91x65cm, XL: 110x70cm(overlapping) XXL: 125x76cm(overlapping)	Analysis 4
Dimension	211*55*50mm	220*140*90mm	Analysis 4
Weight	1.15±0.1kg	1.6Kg	Analysis 4
Work mode	Mode 1 The model is divided into two processes, the first process includes inflating, deflating and holding pressure. The inflating sequence of air chambers of sleeves is: The chamber No.① Inflate and keep pressure three times, deflated, Then the chamber No ② inflate and keep pressure three times, deflated. In the second process, the air pump is always opened, and the air is inflated and deflated according to the following inflating sequence: ①②—①—②-①②—①—②—①—②—①②—①-②—①②—①—②—①—②—① The inflating time is different according to the intensity selected. Mode 2 In this model, at first ,the chamber No. ① inflate and keep pressure four times, then chamber No. ①②are inflated and deflated at the same time. Mode 3 The chamber No. ①② are inflated and deflated at the same time, Then the cycle repeats.	Mode A: In this mode, only a single chamber is inflated at a time. Starting from the chamber ① and working up to the chamber ⑥. Then the cycle repeats. Mode B: In this mode, the chamber ① stays inflated. It gradually adds a chamber until all six chambers are filled with air. Then the cycle repeats. Mode C: In this mode, chamber ① inflates & deflates 4 times, then holds pressure; next chamber ② inflates & deflates 4 times, chamber ①② hold pressure; chamber ③ inflates & deflates 4 times, chamber ②③ hold pressure, chamber ① deflates; chamber ④ inflates & deflates 4 times, chamber ③④ hold pressure, chamber ② deflates; working as this way up to chamber ⑥. Then the cycle repeats. Note: Under this mode, for the FIRST CYCLE, it works as mode B to warm up; from the 2nd cycle on, it works as PULSE Mode C. Mode D: In this mode, all chambers inflates together, and deflates together. Then the cycle repeats	Analysis 5

Analysis 1

Although the treatment time range of subject device is 0 to 30mins, which seems to be smaller than the predicate devices, the default value is 15min which is suitable for daily use. In the process of use, the user can start or stop at any time by the power button on the hand controller, so the difference of Treatment time would not raise adversely impact on safety and effectiveness.

Analysis 2

Although the subject device design and specification parameter between the predicate devices, they are both complied with IEC60601-1, so the minor differences of power source and Power consumption does not raise any new issue of the safety or effectiveness.

Analysis 3

Number of chambers is different, but the application site and treatment pressure range are the same. The minor difference of number of chambers does not raise any new issue of the safety or effectiveness.

Analysis 4

The proposed device is different in appearance, dimension and weight from the predicate device. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference will not affect the substantially equivalency.

Analysis 5

Although the work mode is different, while the difference of work modes just because the inflatable order of the different chambers. The treatment pressure range is the same under different work modes, so the difference of work mode would not raise adversely impact on safety and effectiveness.

Table 3 Safety Comparison

Item	**Proposed Device**	**Predicate Device**	**Remark**
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1,IEC 60601-1-11	Comply with IEC 60601-1,IEC 60601-1-11	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Battery Safety	Comply with IEC 62133-2	Comply with IEC 62133-2	SAME
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Terylene	Not Publicly Available	Analysis
Cytotoxicity	Comply with ISO 10993-5	Comply with ISO 10993-5	SAME
Sensitization	Comply with ISO 10993-10	Comply with ISO 10993-10	SAME
Irritation	Comply with ISO 10993-10	Comply with ISO 10993-10	SAME

Analysis

Although the materials in contact with human skin are different, they all meet the requirements of ISO 10993-5/10 and will not affect product safety.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Air Pressure Foot Massager (SM-512F) is as safe, as effective, and performs as well as or better than the legally marketed predicate device K201935.