January 18, 2022

Xiamen High Top Electronic Technology 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: K212713
Trade/Device Name: Air compression leg massager HY-1117A
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 5, 2022
Received: January 5, 2022

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,

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)*
K212713

Device Name
Air compression leg massager HY-1117A

Indications for Use *(Describe)*
Air compression leg massager HY-1117A is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health.

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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K212713: 510(k) Summary

Type of Submission Traditional

Date Prepared June 25, 2021

Submission Sponsor

Manufacturer Name	Xiamen High Top Electronic Technology Co., Ltd.
Address	F2-5 No. 118 Siming Park, Tong'an Industrial Zone, Xiamen, Fujian, China
Tel	86-15359228717
Email	181492777@qq.com
Contact Person	Liangsan Zhao

Application Correspondent

Company Name	Shanghai Spica Management Consulting Co., Ltd.
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Contact Person	Sam Lin

Device Identification

Trade Name	Air compression leg massager HY-1117A
Regulation Number	21 CFR 890.5650
Classification Name	Massager, Powered Inflatable Tube
Device Classification	Class II
Panel	Physical Medicine
Product Code	IRP
Previous Submissions	**None**

Indications for Use

Air compression leg massager HY-1117A is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health.

Device Description

Air compression leg massager HY-1117A 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 compression leg massager HY-1117A, in medical market, it has a sequential squeezing from distal to proximal, thus help to improve circulation to the treated areas.

Predicate and Reference Device Information

Sponsor	Shenzhen Dongjilian Electronics Co., Ltd.
Trade/Device Name	Air Compression Therapy Device
510(K) number	K193354
Regulation Number	21 CFR 890.5650

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

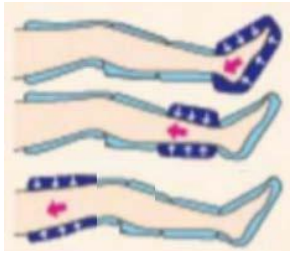
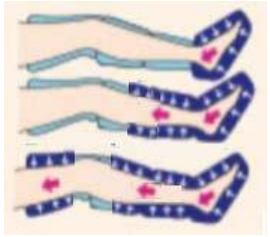
Not Applicable.

Table 6A: Summary of Comparison

	Subject Device	Predicate Device	Differences Discussion
Device name	Air compression leg massager HY-1117A	Air Compression Therapy Device	N/A
510(k) number	K212713	K193354	N/A
Manufacturer	Xiamen High Top Electronic Technology Co., Ltd.	Shenzhen Dongjilian Electronics Co., Ltd.	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	Air compression leg massager HY-1117A is intended for home to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas in people who are in good health.	The Air Compression Therapy Device 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 Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.	Same
Rx or OTC	OTC	OTC	Same

Pressure range	0-240mmHg	0~240mmHg	Same
Treatment time	15 minutes	20 minutes	Similar The treatment time of subject device is smaller than predicate device (K193354), so the difference of treatment time would not raise adversely impact on safety and effectiveness.
Standard	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, IEC 60601-1-2, IEC 60601-1-11, ISO 10993-5, ISO 10993-10	ES 60601-1; IEC60601-1-2; ISO 10993-5: ISO 10993-10; IEC 60601-1-11	Similar
Mode of compression	Sequential	Sequential/ Peristaltic	Same
Power source	100~240V 50/60Hz	100~240V 50/60Hz	Same
Power consumption	24W	12W	Similar
Dimensions (W*H*D)	11*16*24.9inch	10.2×5.9×25.6inch	Similar
Photo			Similar

			Similar
Housing materials	Molded ABS enclosure	Molded ABS enclosure	Same
Number of chambers	3	3	Same
Work mode	Six modes: Full leg 1(F1) Full leg 2(F2) Full leg 3(F3) Separate part 1(M1) Separate part 2(M2) Separate part 3(M3)	Mode 1: Starting with the foot chamber and progressing up the thigh 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 thigh section decompresses, the cycle begins again. Mode 1 follows this pressure sequence:	Although the subject device provides 6 kinds of work mode, the Mode F1, F2, F3, M1, M2, M3 are the similar with predicate device (K193354), while the subject device just have difference about 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.

		 Mode 2: Starting with the foot chamber and progressing up the thigh, each section compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All three sections then decompress simultaneously and the air pressure drops, then cycle begins again. Mode 2 follows this pressure sequence:  Mode 3:	

		include two stage, stage 1: it work according to the method of mode 1, after the stage 1 is completed, it go to stage 2(working according to the method of mode 2) without interruption time until finish the stage 2, then enter next cycle without interruption . Mode1  Mode2 The pressure sequence of mode 3 combines mode 1 and mode 2	
Safety feature	Button on display allows user to stop or pause 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 1-11: 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
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ISO 10993-5: 2009 - Biological Evaluation of Medical Device - Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10: 2010 - Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization

Conclusion

Based on the indications for use, technological characteristics, and non-clinical performance data, “Air compression leg massager HY-1117A (K212713)” is as safe, as effective, and performs as well as the legally marketed predicate devices, “Air Compression Therapy Device (K193354)”. Therefore, the subject device is substantially equivalent to the predicate device.