November 10, 2021

Shenzhen Pango Electronic CO., LTD
℅ Cassie Lee
Manager
Guangzhou Glomed Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K203746
Trade/Device Name: Venen-trainer (Model: FM150, SFM90)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 22, 2021
Received: September 29, 2021

Dear Cassie Lee:

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,

Nicole Gillette
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K203746

Device Name
Venen-trainer (Model: FM150, SFM90)

Indications for Use *(Describe)*
Venen-trainer (Model: FM150, SFM90) is intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. These devices are also intended for the prophylaxis of deep vein thrombosis (DVT).
Intended for use in a home or healthcare setting.

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 for K203746

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.109.

1. Submitter's Information

510(k) Owner's Name: SHENZHEN PANGO ELECTRONIC CO., LTD
Establishment Registration Number: 3006792041
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2. Application Correspondent:

Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

3. Subject Device Information

Type of 510(k): Traditional
Classification Name: Sleeve, Limb, Compressible
Trade Name: Venen-trainer
Model Name: FM150, SFM90
Review Panel: Cardiovascular
Product Code: JOW
Regulation Number: 870.5800
Regulatory Class: 2

4. Predicate Device Information

Sponsor: Bio Compression Systems, Inc.
Trade Name: Sequential Circulators
Classification Name: Sleeve, Limb, Compressible
510(K) Number: K210417
Review Panel: Cardiovascular
Product Code: JOW
Regulation Number: 870.5800
Regulation Class: 2

5. Device Description

Venen-Trainer (model: FM150, SFM90) is a compression therapy device, consists of two leg cuffs with integrated inflation and deflation air cushions, two air hoses and a handheld controller. The working principle is the air inflating and deflating the sleeve sequentially to develop the circulating pressure on the human body. Squeezing the proximal and distal of the limbs to promote blood circulation lymphatic system and improve body microcirculation. Besides, prevent thrombus, reduce limbs drops and this kind disease which is related to blood and lymph circulation directly or indirectly.

The two leg cuffs are each connected to one end of an air hose, and the other end of the two air hoses is connected to the controller. The air pressure controller has a built-in vacuum pump, and the air pressure intensity can be adjusted by the air pressure controller. Turn the knob clockwise to increase the intensity. The timer of FM150 can be switched between three

timings of 10 minutes, 20 minutes and 30 minutes, and the timer of SFM90 is only one timing of 30 minutes.
The two leg cuffs are inflated alternately and will not be inflated simultaneously. In addition, there are hook and loop buckles on the foot cover to adjust the leg cuff to the shape of user's leg.

6. Intended Use / Indications for Use

Venen-trainer (Model: FM150, SFM90) is intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. These devices are also intended for the prophylaxis of deep vein thrombosis (DVT).
Intended for use in a home or healthcare setting.

7. Test Summary

Venen-trainer has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-1-11 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Biocompatibility test according to ISO 10993 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre-Market Submissions and for Software Contained in Medical Devices"

8. Comparison to predicate device and conclusion

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Company	SHENZHEN PANGO ELECTRONIC CO., LTD	Bio Compression Systems, Inc.	--
510 (k)	K203746	K210417	--
Trade Name	Venen-trainer	Sequential Circulators	--
Model	FM150, SFM90	SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL	
Classification Name	Sleeve, Limb, Compressible	Sleeve, Limb, Compressible	Same
Classification	Class II Device, JOW (21 CFR870.5800)	Class II Device, JOW (21 CFR870.5800)	Same
Prescription or OTC	Prescription	Prescription	Same
Intended use	Venen-trainer (Model: FM150, SFM90) is intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. These devices are also intended for the prophylaxis of deep vein thrombosis (DVT). Intended for use in a home or healthcare setting.	The Bio Compression Systems' Sequential Circulators are sequential, pneumatic compression devices intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. Sequential Circulators are also intended for the prophylaxis of deep vein thrombosis (DVT). Intended for use in a home or healthcare setting.	Same
Anatomy	Foot / Calves	Limbs	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device	Verdict
Weight	For model FM150: Approx. 1.6kg (including packaging) For model SFM90: Approx. 1.95kg (including packaging)	• SC-1004-DL, SC-2004-DL: 3.3 lbs. (1.5 kg) • SC-1008-DL, SC-2008-DL: 3.65 lbs. (1.66 kg) • SC-4004-DL: 3.5 lbs. (1.59 kg) • SC-4008-DL: 3.85lbs (1.75 kg)	Similar Note 2
Dimension	For model FM150: 169.7*75.9*37.3mm For model SFM90: 168.3*75.6*33.5mm	• 1000 series: 4.5” x 11.75” x 7.75” (114mm x 298mm x 197mm) • 2000/4000 series: 4.5” x 12” x 7.34” (114mm x 304mm x 186mm)	Similar Note 2
Power	100-240VAC 50/60Hz 0.2A converted to DC 6V 500mA or 6V DC AA batteries LR6 *4	120-240V, 50/60 Hz	Similar Note 2
Treatment Time	For model FM150: 10 min, 20 min, 30 min For model SFM90: 30 min	Continuous or adjustable as follows: • 1000 series: 30-120 minutes adjustable in 30-minute increments • 2000/4000 series: 10-120 minutes in 5-minute increments	Similar Note 2
Cycle Time	60-120s	• 1000 series: 60-120 seconds in 30-second increments • 2000/4000 series: 60-120 seconds in 15-second increments	Same
Interface Pressure Range	0-120mmHg	• 20-100 mmHg, adjustable in 5mmHg increments • 10-120 mmHg, adjustable in 1mmHg increments • 0-120 mmHg, adjustable in 1mmHg increments	Same
Mode of Operation	Continuous	Continuous or adjustable	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

Note 1:
Although the “Anatomy” of subject device is little difference with predicate device, the legs of this anatomy is included in the limbs. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:
Although the “Weight”, “Dimensions”, “Power” and “Treatment Time” of subject device is a little difference with predicate device, they all meet the requirements of safety and performance standard IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. So, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Final Conclusion:

The subject device Venen-trainer (Model: FM150, SFM90) has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device K210417.

9. Date of the summary prepared: November 10, 2021