March 6, 2024

Koge Micro Tech Co., Ltd.
Doris Chiu
Regulatory Affairs
5F., No. 6, Jiankang Rd. 1, Zhonghe Dist.
New Taipei, 23586
Taiwan

Re: K232270
Trade/Device Name: DVT Motion Pneumatic Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 29, 2024
Received: February 7, 2024

Dear Doris Chiu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 M. Gillette -S

Nicole Gillette
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232270

Device Name
DVT Motion Pneumatic Compression Device

Indications for Use *(Describe)*
DVT Motion Pneumatic Compression Device is a prescription device intended for prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in the prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital 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.

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510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: 03/04/2024

5.3 Submitter: Koge Micro Tech Co., Ltd.

Address: 5F., No. 6, Jiankang Rd. 1, Zhonghe Dist., New Taipei City 23586, Taiwan (R.O.C)
Phone: +886-2-77381338
Contact: Doris Chiu
(doris_chiu@koge.com)

5.4 Identification of the Device:

Proprietary/Trade name:	DVT Motion Pneumatic Compression Device
Classification Product Code:	JOW
Regulation Number:	870.5800
Regulation Description:	Sleeve, Limb, Compressible
Review Panel:	Cardiovascular
Device Class:	II
Basis for the Submissions	New Device

5.5 Identification of the Predicate Device:

Predicate Device Name:	VascuEase IC-1200-WH
Applicant:	Bio Compression Systems. Inc.
Classification Product Code:	JOW
Regulation number:	870.5800
Device Class:	II
510(k) Number:	K180248

5.6 Indications for Use / Intended Use of the Device

DVT Motion Pneumatic Compression Device is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in the prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital setting.

5.7 Description of the Device

The DVT Motion Pneumatic Compression Device is a portable, rechargeable battery-powered device intended for prescribed home use or hospital use to help prevent Deep Vein Thrombosis (DVT) in patients by stimulating blood flow.

This is accomplished using an electronically controlled pump delivering a set amount of air to the leg garment that compresses the calf and aids blood flow through the lower extremities.

The pump will inflate to a preset pressure of 50mmHg and deflate once this pressure is reached. The cycle continues until the unit is turned off.

The tube free solution comes complete with a fully integrated lithium ion battery that supplies over 18 hours of treatment on a single charge, assuring that patients can be transported easily from the hospital to their homes without interruptions in treatment.

Package contents:

- a pair of DVT Motion Pneumatic Compression Pumps
- a pair of leg garments
- a charger (including an adaptor)
- a set of instructions

5.8 Non-clinical Testing

A series of non-clinical safety and performance studies were conducted on the subject device. The following tests and studies were according to the related recognized consensus standards.

- Shelf Life Test
- Biocompatibility
  - *In Virto* Cytotoxicity Test
  - Skin Sensitization Study
  - Skin Irritation Test
- Software Validation
- Electromagnetic compatibility and electrical safety
- Performance
  - Alert Test
  - Discharge and Charge
  - Inflation and Deflation Time Test
  - System Leakage Test
  - System Pressure Test
- Usability test

All the test results demonstrate DVT Motion Pneumatic Compression Device meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence. The safety and effectiveness of the finished DVT Motion Pneumatic Compression Device have been established through previous non-clinical performance testing.

5.10 Substantial Equivalence Determination

The DVT Motion Pneumatic Compression Device submitted in this 510(k) file is substantially equivalent in intended use, safety and performance claims to the cleared device, VascuEase IC-1200-WH (K180248). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	Koge Micro Tech Co., Ltd.	Bio Compression Systems, Inc.	
Trade Name	DVT Motion Pneumatic Compression Device	VascuEase IC-1200-WH	
510(k) No.	(to be assigned)	K180248	
Intended Use	DVT Motion Pneumatic Compression Device is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in the prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital setting.	VascuEase is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital setting.	***Same***
Principle of Operation	Intermittent Pneumatic Compression	Intermittent Pneumatic Compression	***Same***
Type of Use	Prescription Use	Prescription Use	***Same***
Weight	260 g ± 30 g (0.57 ± 0.066 pounds)	0.7 pounds	***Equivalent*** Different but the

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	Koge Micro Tech Co., Ltd.	Bio Compression Systems, Inc.	
Trade Name	DVT Motion Pneumatic Compression Device	VascuEase IC-1200-WH	
510(k) No.	(to be assigned)	K180248	
			performances of the subject device are not affected and meet the requirements. Therefore, it would not affect the equivalence.
Dimensions	140 mm x 77 mm x 40 mm (5.51 x 3.03 x 1.57 inches)	5.3 x 2.7 x 1.5 inches	***Equivalent*** Different but the performances of the subject device are not affected and meet the requirements. Therefore, it would not affect the equivalence.
Number of Segments in garment	1	1	***Same***

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	Koge Micro Tech Co., Ltd.	Bio Compression Systems, Inc.	
Trade Name	DVT Motion Pneumatic Compression Device	VascuEase IC-1200-WH	
510(k) No.	(to be assigned)	K180248	
Cycle Time	60 ± 10 seconnds (Inflation time: 15 seconds; Deflation time: 45 seconds)	Inflation Time: 15 seconds Deflation Time: 45 seconds	***Same***
Pressure	50 mmHg ± 20 %	50 mmHg	***Same***
Pressure Adjustment	N/A	N/A	***Same***
Pressure Display	No	No	***Same***
Power Requirement	Rechargeable battery	Rechargeable battery	***Same***
Mobility	Portable, worn	Portable, worn	***Same***

5.11 Similarity and Difference

The DVT Motion Pneumatic Compression Device is compared with *VascuEase IC-1200-WH*. The subject device has same intended use, principal of operation, type of use and performance, and similar safety with the predicate device. No specifications are significantly different between these two devices.

Furthermore, the subject device has undergone other safety and performance tests, and the results complied with the testing standards. Therefore, any differences between the subject device and the predicate device are insignificant and do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device as it claims.

5.12 Conclusion

After analyzing non-clinical laboratory studies, safety and performance testing data, it can be concluded that the DVT Motion Pneumatic Compression Device is substantially equivalent to the predicate device.