June 25, 2026

Vistar Medical Supplies Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K253386
Trade/Device Name: DVT Garment
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 14, 2026
Received: May 15, 2026

Dear Boyle 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Meaghan Erlewein -S

For 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253386

Please provide the device trade name(s).

DVT Garment

Please provide your Indications for Use below.

The DVT Garment is a medical device designed to prevent deep vein thrombosis (DVT) and improve blood circulation in the lower extremities. It must be used in conjunction with a compatible DVT therapy machine.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K253386

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's information

Name: Vistar Medical Supplies Co.,Ltd.
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Date of Preparation: June.17, 2026

Designated Submission Correspondent

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2.0 Device information

Trade name:	DVT Garment
Common name:	DVT Garment
Classification name:	Sleeve, limb, compressible

3.0 Classification

Production code:	JOW
Regulation number:	21 CFR 870.5800
Classification:	Class II
Panel:	Cardiovascular

4.0 Predicate device information

Predicate Device 1:

Manufacturer:	B & J Manufacturing Ltd.
Trade/Device Name:	B&J DVT Calf/Thigh Garments, Models 801/830 Series
510(k) number:	K201532

Predicate Device 2:
Manufacturer: B & J Manufacturing Ltd.
Trade/Device Name: B&J DVT Foot Garments, Models 820 Series
510(k) number: K201547

5.0 Indication for Use Statement

The DVT Garment is a medical device designed to prevent deep vein thrombosis (DVT) and improve blood circulation in the lower extremities. It must be used in conjunction with a compatible DVT therapy machine.

6.0 Device description

The DVT Garments are compression devices. When the devices are attached to a pump system, they provide intermittent, sequentially gradient pressure to a patient foot/calf/thigh for the prevention of deep vein thrombosis (DVT).
When the compression sleeve is inflated, the veins collapse which forces blood to move upward toward the heart. After compression is complete, the sleeves deflate which allows the veins to reopen and bring oxygenated blood to the foot, calf or thigh. This device is a disposable single patient use products.
The DVT garments are supplied as pairs. The three-chamber garments include one left and one right garment, identified by “L” and “R” respectively. The single-chamber garment is not side-specific.

Series	Description	Model	Size	Circumference (inch)
Sequential Garment (3 chambers)	Calf Garment	DVT10C31	Extra Small	≤14"
		DVT10C32	Small	14"-18"
		DVT10C33	Medium	18"-24"
		DVT10C34	Large	24"-30
		DVT10C35	Extra Large	26"-35"
	Foot Garment	DVT10F31	Medium	≤13"
		DVT10F32	Large	≤16"
	Thigh Garment	DVT10T31	Extra Small	≤14"
		DVT10T32	Small	14"-20"
		DVT10T33	Medium	20"-25"
		DVT10T34	Large	25"-30"
		DVT10T35	Extra Large	30"-32"
Intermittent Garment (1 chamber)	Calf Garment	DVT10C11	Extra Small	≤14"
		DVT10C12	Small	14"-18"
		DVT10C13	Medium	18"-24"
		DVT10C14	Large	24"-30

		DVT10C15	Extra Large	26"-35"
	Foot Garment	DVT10F11	Medium	≤13"
		DVT10F12	Large	≤16"
	Thigh Garment	DVT10T11	Extra Small	≤14"
		DVT10T12	Small	14"-20"
		DVT10T13	Medium	20"-25"
		DVT10T14	Large	25"-30"
		DVT10T15	Extra Large	30"-32"

The subject device is supplied in 2 series:

7.0 Technological Characteristic Comparison Table

The subject device DVT Garment is substantially equivalent to the predicate device with respect to the intended use, technology and construction. The differences between the predicate and the subject device are minor and any risks have been mitigated through testing. The below table summarizes the differences between the subject and predicate device.

Table1-General Comparison between Subject device and Predicate Device K201532

Item	**Subject device K253386**		**Predicate device 1 K201532**		**Remark**
Trade/Device Name	DVT Garment		B&J DVT Calf/Thigh Garments, Models 801/830 Series		/
Manufacturer	Vistar Medical Supplies Co.,Ltd.		B & J Manufacturing Ltd.		/
Class &Code	Class II JOW 870.5800		Class II JOW 870.5800		Same
Intended Use / Indication for Use	The DVT Garment is a medical device designed to prevent deep vein thrombosis (DVT) and improve blood circulation in the lower extremities. It must be used in conjunction with a compatible DVT therapy machine.		The B&J DVT Calf/Thigh Garments, Models 801/830 Series are designed to increase venous blood flow in at risk patients in order to help lower the risk of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).		Same
Type of Use	Prescription Use		Prescription Use		Same
Sequencing	Sequential	Intermittent	Sequential	Intermittent	Same
Model, Size and	Calf Garment:	Calf Garment:	Calf Garment:	Calf Garment:	Similar, the

Type	DVT10C31, Extra Small, ≤ 14" DVT10C32, Small, 14"-18" DVT10C33, Medium, 18"-24" DVT10C34, Large, 24"-30 DVT10C35, Extra Large, 26"-35"	DVT10C11, Extra Small, ≤ 14" DVT10C12, Small, 14"-18" DVT10C13, Medium, 18"-24" DVT10C14, Large, 24"-30 DVT10C15, Extra Large, 26"-35"	801PSQ, Small, 14'' 801MSQ, Medium, 18'' 801LSQ, Large, 24'' 801BSQ, Extra Large, 32''	801P, Small, 14'' 801M, Medium, 18'' 801L, Large, 24'' 801B, Extra Large, 32''	difference doesn't affect the substantial equivalence with the predicate.
	Thigh Garment: DVT10T31, Extra Small, ≤ 14" DVT10T32, Small, 14"-20" DVT10T33, Medium, 20"-25" DVT10T34, Large, 25"-30" DVT10T35, Extra Large, 30"-32"	Thigh Garment: DVT10T11, Extra Small, ≤ 14" DVT10T12, Small, 14"-20" DVT10T13, Medium, 20"-25" DVT10T14, Large, 25"-30" DVT10T15, Extra Large, 30"-32"	Thigh Garment: 830SSQ, Small, 14'' 830MSQ, Medium, 29'' 830LSQ, Large, 36'' 830BSQ, Extra Large, 42''	Thigh Garment: 830S, Small, 14'' 830M, Medium, 29'' 830L, Large, 36'' 830B, Extra Large, 42''	
Material	Outside material: White Nylon coated TPU film, Patient side: White non-woven Fabric coated with TPU film, Air hose: PVC tube, Connector: Plastic.		Nylon loop, polyurethane foam, polyster tricot, TPU film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread	Nylon loop, polyster loop, polyurethane foam, polyster tricot, PVC film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread	Similar
Inflation/deflation cycle times	11-13 seconds / 48 seconds		12 seconds / 48 seconds	12 seconds / 48 seconds	Similar
Pressure ranges	45, 40, and 30mmHg		45, 40, and 30mmHg	40mmHg	Same

Table2-General Comparison between Subject device and Predicate Device K201547

Item	Subject device K253386		Predicate device 2 K201547		Remark
Trade/Device Name	DVT Garment		B&J DVT Foot Garments, Models 820 Series		/
Manufacturer	Vistar Medical Supplies Co.,Ltd.		B & J Manufacturing Ltd.		/
Class &Code	Class II JOW 870.5800		Class II JOW 870.5800		Same
Intended Use / Indication for Use	The DVT Garment is a medical device designed to prevent deep vein thrombosis (DVT) and improve blood circulation in the lower extremities. It must be used in conjunction with a compatible DVT therapy machine.		The B&J DVT Foot Garments, Models 820 Series are external pneumatic compression device intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.		Same
Type of Use	Prescription Use		Prescription Use		Same
Sequencing	Sequential	Intermittent	Sequential	Intermittent	Same
Model, Size and Type	Foot Garment: DVT10F31, Medium, ≤13" DVT10F32, Large, ≤16"	Foot Garment: DVT10F11, Medium, ≤13" DVT10F12, Large, ≤16"	Foot Garment: 820MSQ, Medium, 13'' 820LSQ, Large, 16''	Foot Garment: 820M, Medium, 13'' 820L, Large, 16''	Similar, the difference doesn't affect the substantial equivalence with the predicate.

Material	Outside material: White Nylon coated TPU film, Patient side: White non-woven Fabric coated with TPU film, Air hose: PVC tube, Connector: Plastic.	Nylon loop, polyurethane foam, polyster tricot, TPU film, PVC tube, nylon velcro, polyster & cotton binding, nylon thread		Similar
Inflation/deflation cycle times	11-13 seconds / 48 seconds	12 seconds / 48 seconds	12 seconds / 48 seconds	Similar
Pressure ranges	≤130mmHg	120mmHg+10/-5mmHg	120mmHg+10/-5mmHg	Analysis

The subject device has the same intended use, indications for use, technological characteristics, principles of operation, and performance specifications as the predicate device.

Analysis:
All differences between the subject device and the predicate devices (including material composition, pressure parameter range, and inflation/deflation cycle control mode) are either "optimizations for functional flexibility" (e.g., adaptive inflation/deflation cycles) or "upgrades for material performance" (e.g., TPU film replacing PVC film). These differences do not change the working principle (simulating muscle contraction through intermittent/sequential pressure) or key performance indicators (pressure accuracy, airtightness, material biocompatibility) of the device, nor do they introduce new safety risks (such as skin irritation, structural rupture, or pressure overload).

Despite of the above differences, the two devices all completed the performance tests. In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

8.0 Summary of Non-Clinical Testing

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 performance testing:

- Dimensions/Appearance Test
- Leakage Test
- Lifetime Test
- Pressure Resistance Test
- Tensile Strength Test
- Inflation and Deflation Test

Biocompatibility of patient-contacting parts

- Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.
- Skin Sensitization per ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.
- Skin Irritation per ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests For Irritation.

All tests met the pre-determined acceptance criteria.

9.0 Summary of Clinical Testing

No clinical study implemented for the DVT Garment.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicate devices and raises no new questions of safety or effectiveness.