February 27, 2025

Vascutek Ltd.
Ryan King
Senior Regulatory Affairs Associate
Newmains Avenue
Inchinnan, Renfrewshire PA4 9RR
United Kingdom

Re: K241550
Trade/Device Name: Gelweave™ Vascular Prostheses
Regulatory Class: Class II
Product Code: DSY
Dated: May 31, 2024
Received: May 31, 2024

Dear Ryan King:

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.

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,

Rohini Retarekar -S

for Carmen Gacchina Johnson, Ph.D.
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)*
K241550

Device Name
Gelweave™ Vascular Prostheses

Indications for Use *(Describe)*
Gelweave Vascular Prosthesis (with the exception of Valsalva variant) are indicated for the repair or replacement of damaged and diseased vessels of the thoracic and abdominal aorta in cases of aneurysm, dissection or occlusive disease. Branched configurations can also be used for debranching, i.e. reconstruction of the aortic vessels and associated Hybrid procedures. Hybrid procedures are defined as a treatment combination employing open surgical debranching with endovascular aortic repair.

Gelweave Valsalva Vascular Prosthesis are indicated for the repair or replacement of damaged and diseased thoracic aorta, such as aortic root replacement in cases of aneurysm or dissection.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K241550

February 26, 2025

This 510(k) Summary is being submitted in accordance with 21 CFR 807.92.

CONTACT DETAILS

Applicant Name:	Vascutek Ltd.
Applicant Address:	Newmains Avenue Inchinnan Renfrewshire PA49RR United Kingdom
Applicant Contact Telephone:	+44 141 343 063
Applicant Contact:	Mr. Ryan King
Applicant Contact Email:	r.king@terumoaortic.com
Date of Submission:	May 31, 2024

DEVICE NAME

Device Trade Name:	Gelweave™ Vascular Prostheses
Common Name:	Vascular graft prosthesis
Classification Name:	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter
Regulation Number:	870.3450
Product Code(s):	DSY

LEGALLY MARKETED PREDICATE DEVICES

Predicate #:	K162794
Predicate Trade Name:	Vascutek Gelweave™ Vascular Grafts
Product Code:	DSY

DEVICE DESCRIPTION SUMMARY

Gelweave™ vascular prostheses are gelatin sealed woven polyester prostheses designed for vascular repair. The Gelweave™ polyester vascular prostheses family, which is the subject of this pre-market notification, is based on woven polyester textile technology.

INTENDED USE/INDICATIONS FOR USE

Gelweave Vascular Prosthesis (with the exception of Valsalva variant) are indicated for the repair or replacement of damaged and diseased vessels of the thoracic and abdominal aorta in cases of aneurysm, dissection or occlusive disease. Branched configurations can also be used for debranching, i.e. reconstruction of the aortic vessels and associated Hybrid procedures. Hybrid procedures are defined as a treatment combination employing open surgical debranching with endovascular aortic repair.

Gelweave Valsalva Vascular Prosthesis are indicated for the repair or replacement of damaged and diseased thoracic aorta, such as aortic root replacement in cases of aneurysm or dissection.

TECHNOLOGICAL COMPARISON

The subject and predicate device have similar design and identical intended use. Differences in technological characteristics include change in supplier of the gelatin used to seal the graft, change in yarn supplier, implementation of a new sterilization suite and the addition of new device configurations. Both this and the predicate device are based on woven polyester textile technology. They use the same materials (PET yarn and bovine gelatin) and have the same principles of operation.

The nonclinical testing performed, including bench testing, sterilization, packaging, shelf-life, biocompatibility testing, chemical characterization and an animal performance study, have demonstrated that the device is substantially equivalent to the predicate device.

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Nonclinical testing, including bench testing, sterilization, packaging, shelf-life, biocompatibility testing, chemical characterization and an animal performance study, have been conducted to demonstrate equivalency. No clinical testing was necessary to demonstrate substantial equivalence.