April 6, 2021

Vascutek Ltd
Chirag Merchant
Senior Regulatory Affairs Associate
Newmains Avenue, Inchinnan
Renfrewshire PA4 9RR
Scotland, UK

Re: K202703
Trade/Device Name: Gelsoft Plus ERS Vascular Grafts
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: February 12, 2021
Received: February 25, 2021

Dear Chirag Merchant:

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,

Rohini Retarekar -S

for Carmen Gacchina Johnson, PhD
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)*
K202703

Device Name
Vascutek Gelsoft Plus ERS Vascular Graft

Indications for Use *(Describe)*
Indicated for extra anatomical vascular repair, primarily for axillo-femoral/bi-femoral bypass and femoro- popliteal reconstruction.

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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K202703

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510 (k) Summary

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

Submitter:	Vascutek Ltd Newmains Avenue Inchinnan Renfrewshire PA4 9RR Scotland, UK Tel: +44 (0) 141 812 555
Contact:	Chirag Merchant Senior Regulatory Affairs Associate Tel: +44 (0) 141 812 555 Email: c.merchant@terumoaortic.com
Date of Preparation:	April 2, 2021
Trade Name:	Vascutek Gelsoft Plus ERS Vascular Graft
Common or Usual Name:	Vascular Graft Prosthesis
Classification Name:	Prosthesis, vascular graft, of 6mm and greater diameter
Product Code:	DSY
Regulation Number:	21 CFR 870. 3450
Device Class:	II

THE QUEEN'S AWARDS FOR ENTERPRISE: INNOVATION 2016

Identification of the legally marketed device to which equivalence is being claimed:
Vascutek Ltd. are claiming equivalence to the following legally marketed devices:

- Vascutek Gelsoft Plus ERS (K034010).

Device Description:
Gelsoft Plus ERS grafts are an externally reinforced (ERS), gelatin-sealed, knitted polyester grafts.

Vascutek's polyester vascular prosthesis family is based on a polyester textile technology. The starting point for all products is polyester yarn. This is fabricated into tubular form by knitting. This is referred to as the base fabric and exists in a variety of designs to meet particular end uses. Further processing is designed to retain the tubular form of the graft e.g. crimping and addition of an external polypropylene support. In Gelsoft Plus ERS, this external polypropylene support is to provide kink resistance and a smooth flow surface for extra-anatomical applications. The polypropylene support may be peeled where it extends to the ends of the prosthesis, in order to facilitate the fashioning of the anastomosis. Additional branches are also attached in a variety of configurations. The last process is impregnation with a bovine derived gelatin sealant. This process fills the gaps between threads of the polyester base graft and eliminates the need for pre-clotting of the graft prior to implant.

Intended Use:

The intended use of the Gelsoft Plus ERS vascular graft is for the extra-anatomical vascular repair.

Indications for Use:

Vascutek Gelsoft Plus ERS Graft is indicated for extra anatomical vascular repair, primarily for axillo-femoral/bi-femoral bypass and femoro- popliteal reconstruction.

Gelsoft Plus ERS AX -FEM Vascular Graft: Indicated for vascular repair i.e. primarily for axillo-femoral bypass procedures & femoral- popliteal reconstruction in aneurysmal & occlusive disease of the arteries.

THE QUEEN'S AWARDS
FOR ENTERPRISE:
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2016

Gelsoft Plus ERS FEM- FEM Vascular Graft: Indicated for vascular repair i.e. primarily for femoro-femoral bypass procedures in aneurysmal & occlusive disease of the arteries.

Gelsoft Plus ERS AX- BIFEM Vascular Graft: Indicated for vascular repair i.e. primarily for axillo-bi-femoral bypass procedures in aneurysmal & occlusive disease of the arteries.

Intended Patient Population:

Patients requiring extra anatomical vascular repair whenever knitted polyester grafts are normally indicated, primarily for axillo-femoral/bi-femoral bypass and femoro-popliteal reconstruction in aneurysmal & occlusive disease of the arteries.

They are contraindicated for use in patients with a sensitivity to polyester or materials of bovine origin. They are contraindicated for coronary vascular repair, blood access fistula (e.g. haemodialysis) and pulmonary shunting. They are contraindicated for thoracic use. They are contraindicated for use in the pulmonary positions, use in arteriovenous shunting or cardiovascular patching.

Technological Characteristics:
Equivalency is based on identical design, technology, construction and intended use.

The only change is that the gelatin used to seal the grafts will be purchased from a new supplier.

The nonclinical testing performed, including physical bench, biocompatibility, chemical characterisation and an animal performance study, have demonstrated that the device is substantially equivalent to the predicate device.

THE QUEEN'S AWARDS
FOR ENTERPRISE:
INNOVATION
2016