DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 14, 2017

Vascutek Ltd.
Mr. Neil McLachlan
Head of Regulatory Affairs
Newmains Avenue
Inchinnan
Renfrewshire, PA4 9RR
United Kingdom

Re: K162803
Trade/Device Name: Gelseal Vascular Grafts, Gelsoft Vascular Grafts, Gelsoft Plus Vascular Grafts
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: June 15, 2017
Received: June 16, 2017

Dear Mr. Neil McLachlan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162803

Device Name
Gelseal™ Vascular Grafts

Indications for Use *(Describe)*
Indicated for replacement or bypass of abdominal arteries afflicted with aneurysmal or occlusive disease.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162803

Device Name
Gelsoft™ Vascular Grafts

Indications for Use *(Describe)*
Indicated for abdominal and peripheral vascular repair, i.e. replacement or bypass in aneurysmal and occlusive disease of arteries.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162803

Device Name
Gelsoft™ Plus Vascular Grafts

Indications for Use *(Describe)*
Indicated exclusively for vascular repair of damaged and diseased vessels of the abdomen, i.e. replacement or bypass in aneurysmal and occlusive disease of abdominal arteries.

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)

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K162803

510 (k) Summary

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

Submitter:

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Date of Preparation: 04 July 2017

Trade Name:

Vascutek Gelseal™ Vascular Grafts
Vascutek Gelsoft™ Vascular Grafts
Vascutek Gelsoft™ Plus Vascular Grafts

Common or Usual Name: Vascular Prosthesis

Classification Name: Vascular Graft Prosthesis

Product Code: DSY

Regulation Number: 21 CFR 870.3450

Device Class: II

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

- Gelseal™ Vascular Graft (P890045)
- Gelsoft™ Vascular Prosthesis (Abdominal Repair Indication) (P890045/S001)
- Gelsoft™ Vascular Prosthesis (Peripheral Repair Indication) (K990503)
- Gelsoft™ Plus Vascular Graft (K955230)

Device Description

Gelseal, Gelsoft and Gelsoft Plus vascular prostheses are gelatin sealed knitted polyester prostheses, designed for vascular repair.

The Vascutek Gelseal, Gelsoft and Gelsoft Plus polyester vascular prosthesis family, which is the subject of this pre-market notification, is based on knitted polyester textile technology.

Indications for Use

The indications for use for each model are identical to each predicate and are described below:

> **Gelseal™ Vascular Prostheses:** *"Indicated for replacement or bypass of abdominal arteries afflicted with aneurysmal or occlusive disease."*
>
> **Gelsoft™ Vascular Prostheses:** *"Indicated for abdominal and peripheral vascular repair, i.e. replacement or bypass in aneurysmal and occlusive disease of arteries."*
>
> **Gelsoft™ Plus Vascular Prostheses:** *"Indicated exclusively for vascular repair of damaged and diseased vessels of the abdomen, i.e. replacement or bypass in aneurysmal and occlusive disease of abdominal arteries."*

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 and biocompatibility testing, chemical characterisation and an animal performance study, have demonstrated that the device is substantially equivalent the predicate devices.