July 8, 2020

Vascutek Ltd
Heidi Forsyth
Regulatory Affairs Associate
Newmains Avenue
Inchinnan, Renfrewshire PA4 9RR
United Kingdom

Re: K200955
Trade/Device Name: Vascutek Gelseal Patch, Vascutek Gelsoft Patch, Vascutek Thin Wall Carotid Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: April 6, 2020
Received: April 9, 2020

Dear Heidi Forsyth:

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,

for Rachel Neubrander
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200955

Device Name
Vascutek Cardiovascular Fabric:
Vascutek Gelseal Patch, Vascutek Gelsoft Patch, Vascutek Thin Wall Carotid Patch

Indications for Use *(Describe)*
Vascutek Cardiovascular Fabric is indicated for vascular or cardiovascular repair whenever knitted polyester fabrics are normally indicated.

Due to its particularly high strength, Gelseal is especially suitable for thoracic use whereas the softer handle of the Gelsoft makes it ideal for peripheral use. The Thin Wall fabric is designed for patch closure after endarterectomy, particularly of the carotid 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)

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

"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."

TERUMO Aortic

Vascutek Ltd
Newmains Avenue, Inchinnan
Renfrewshire PA4 9RR
Scotland, UK

Tel. +44 (0) 141 812 5555
terumoaortic.com

K200955

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 5555

Contact:

Heidi Forsyth
Regulatory Affairs Associate
Tel: +44 (0) 141 812 5555
Email: h.forsyth@terumoaortic.com

Date of Preparation:

03 April 2020

Trade Name:

Vascutek Gelseal™ Cardiovascular Fabric Patches
Vascutek Gelsoft™ Cardiovascular Fabric Patches
Vascutek Thin Wall Carotid Patch

Common or Usual Name:

Cardiovascular Patch

Product Code:

DXZ

Regulation Number:

21 CFR 870: 3470

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 Cardiovascular Fabric:

- Vascutek Gelseal™ Patch (K963611)
- Vascutek Gelsoft™ Patch (K963611)
- Vascutek Thin Wall Carotid Patch (K963611)

Device Description

The Vascutek Cardiovascular Fabric are a range of gelatin sealed, knitted, polyester patch fabrics. The range consists of three different patch fabrics which are manufactured using identical materials, processes and procedures but which, because of slight differences in the pattern of the base fabric, exhibit different physical characteristics. This range of products is provided in order to give the implanting surgeon a choice of several different fabrics from which they can chose the most suitable according to their own preferences and according to specific demands of any given surgical situation.

Two of the patches, Gelseal™ and Gelsoft™, are based on fabrics which are currently used in Vascutek's range of tubular vascular prostheses, which have received Premarket approval from the FDA. The only difference between the cardiovascular fabrics and the tubular grafts is that the patches are produced in flat, patch formats (i.e. square or rectangular) and have not been subjected to the crimping process which is used in the production of the tubular prostheses. With this single exception, the manufacturing facilities, equipment, processes and the quality control processes and procedures are identical to those used in the manufacture of the Gelseal™ and Gelsoft™ vascular prostheses.

The third type of patch, the Thin Wall Carotid Patch, is also manufactured using the identical materials, processes and procedures as the other cardiovascular patches but with a slightly modified knit pattern. This new structure has been developed in order to maintain the physical characteristics necessary for general cardiovascular patching but with a reduced wall thickness and characteristics which make it ideally suited to use for parching carotid arteries after endarterectomy procedures.

Intended Use

The intended use of the Vascutek Cardiovascular Fabric is for vascular patch grafting and for intracardiac patching.

THE QUEEN'S AWARDS FOR ENTERPRISE: INNOVATION 2016

The Thin Wall Carotid Patch is, in addition, indicated for patch closure after endarterectomy, particularly of the carotid arteries.

Indications for Use

Vascutek Cardiovascular Fabric is indicated for vascular or cardiovascular repair whenever knitted polyester fabrics are normally indicated.

Due to its particularly high strength Gelseal is especially suitable for thoracic use whereas the softer handle of the Gelsoft makes it ideal for peripheral use. The Thin Wall fabric is designed for patch closure after endarterectomy, particularly of the carotid arteries.

Intended Patient Population

Gelseal and Gelsoft Patches: Patients requiring repair of vascular or cardiovascular vessels, in particular thoracic repair for Gelseal Patches and peripheral repair in the case of Gelsoft. They are contraindicated for use in patients with a sensitivity to polyester or materials of bovine origin.

Thin Wall Carotid Patches: Patients requiring repair of vascular or cardiovascular vessels, in particular patch closure after endarterectomy of the carotid arteries. They are contraindicated for use in patients with a sensitivity to polyester or materials of bovine origin.

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, biocompatibility testing, chemical characterisation and an animal performance study, have demonstrated that the device is as safe, as effective, and performs as well as the predicate devices.

THE QUEEN'S AWARDS FOR ENTERPRISE: INNOVATION 2016