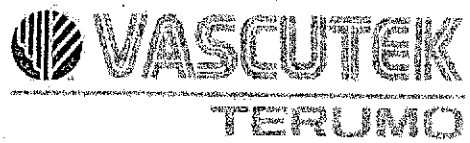
K090987



JUN 19 2009

VASCUTEK Ltd.
a TERUMO Company
Newmains Avenue
Inchinnan
Renfrewshire, PA4 9RR
Scotland

Tel: (+44) (0)141 812 5555
Fax: (+44) (0)141 812 7650
www.vascutek.com

510(k) SUMMARY

VASCUTEK GELWEAVE™ BRANCHED VASCULAR GRAFTS (K952293) AND GELWEAVE SIENA™ VASCULAR GRAFTS WITH (K060142) AND WITHOUT (K040829) RADIOPAQUE MARKERS

Date prepared: 2nd of June 2009
Prepared in accordance with CFR21 Part 807, Sec. 807.92: Content and format of a 510(k) summary.

Common/Usual Name :	Prosthesis, vascular graft
Proprietary Name(s) :	Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers
Classification Name :	Prosthesis, vascular graft, of 6mm and greater diameter
Classification :	The Food and Drug Administration has classified these devices as Class II devices under classification 21 CFR 870.3450. Classification, DSY.
Applicant and : 510(k) submitter/ contact	Karen Kelso Regulatory Affairs Manager Vascutek Ltd. Newmains Avenue Inchinnan Industrial Estate Renfrewshire, Scotland PA4 9RR, United Kingdom Phone: +44 (141) 814 5527 Fax: +44 (141) 814 3431

Device Predicates:

Predicate Device Name	FDA Clearance Date	510(k)
Gelweave™ grafts	19th December 1995	K952293
Gelweave Siena™ grafts without radioapque markers	20th May 2004	K040829
Gelweave Siena™ grafts with radiopaque markers	6th February 2006	K060142

* **NOTE:** Gelweave Branched Grafts - Documentation submitted to Dorothy Abel, FDA, dated 21st November 2001, regarding Vascutek's decision not to submit a 510k for branched Gelweave grafts. This decision utilised FDA Guidance document (K97-1) "Deciding when to submit a 510k for an existing device".

Device Description:
The design and all other properties of the Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers remain unchanged. The Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers function as vascular grafts manufactured from standard polyester and gelatin sealant technologies.

Additional images and information are provided in the catalogue number table presented in Table 3 of this 510(k) submission.

Vascutek Gelweave™ vascular grafts were cleared by FDA on the 19th of December 1995 (K952293). The cleared indications for use were "*Repair or replacement of damaged and diseased vessels of the abdomen and thoracic aorta in cases of aneurysm, dissection or coarctation*".

The branched versions of the Gelweave™ vascular grafts were later made available to also accommodate reconstruction of the associated side vessels and allow intra-operative attachment to cardiopulmonary bypass. This is information clearly detailed in the product Instructions for Use.

In 2004 Vascutek received 510(k) clearance for the Siena™ grafts without radiopaque markers, followed by Siena™ grafts with radiopaque markers in 2006. The intention of the radiopaque markers was to aid *in vivo* visualisation. The branches present on the Gelweave Siena™ grafts, like all other Gelweave™ branched grafts was to accommodate reconstruction of the associated branch vessels and also intra-operative attachment to cardiopulmonary bypass. The cleared indications for use were; "*Repair or replacement of damaged and diseased vessels of the thoracic aorta in cases of aneurysm, dissection or coarctation*". This is clearly detailed in the 510(k) cleared product Instructions for Use.

As stated, the presence of side branches allows accommodation of aortic side vessel reconstruction as well as the ability to attach the patient to cardiopulmonary bypass. It is evident from the available literature and clinical opinion that it is also considered standard practice to use branched polyester vascular grafts to undertake debranching and associated Hybrid procedures. These procedures allow reconstruction of the aortic side vessels at the same time as repair of the aortic aneurysm by using standard polyester vascular grafts in combination with endovascular devices, usually in a single procedure.

Vascutek are therefore requesting FDA clearance to make reference to debranching and associated Hybrid procedures for the Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers in the product labelling, specifically the indications for use, product Instructions for Use and associated marketing literature.

There are no other changes to the products i.e. there are no changes to the design, materials, packaging, sterilisation, shelf life or any other parameters. The only change is a request for an expanded indication for use. The grafts remain as finished products, provided sterile for single use only.

Intended Use:
The intended use for the Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers is currently;

Gelweave™ branched vascular grafts:
"Repair or replacement of damaged and diseased vessels of the abdomen and thoracic aorta in cases of aneurysm, dissection or coarctation".

Gelweave Siena™ vascular grafts with and without radiopaque markers:
"Repair or replacement of damaged and diseased vessels of the thoracic aorta in cases of aneurysm, dissection or coarctation".

The subject of this 510(k) is to request FDA clearance to expand this intended use as follows;

"Gelweave™ branched vascular grafts, including Siena™ grafts 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.

As stated, it is evident from the literature and clinical opinion that it is considered standard practice to use branched polyester vascular grafts to undertake debranching and associated Hybrid procedures. These procedures do not change the overall intended use of the grafts, which are still used in open heart surgery to repair or replace a diseased and damaged aorta and associated vessels.

The difference is therefore not critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the devices. The difference also does not affect the safety and effectiveness of the device when used as labelled.

Principles of Operation and Technology:
Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers are used to repair or replace a diseased and damaged aorta and associated vessels.

Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers are intended only for use in the hospital operating room by suitably qualified surgeons.

Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers provided sterile by ethylene oxide for single use only.

There devices have the same technological characteristics as the predicates i.e. there are no changes to the Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers other than the request for an expanded indication.

Performance: The performance of the Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers remains unchanged. The grafts are still used in open heart surgery to repair or replace a diseased and damaged aorta and associated vessels.

Bench Testing: For verification purposes testing was undertaken to demonstrate that there was no change in the sealing properties of the Gelweave™ branched vascular grafts as a result of introduction and manipulation of an endovascular delivery catheter via a side branch. A 26 F introducer was inserted into the 10mm side branch of 21 Gelweave grafts. The introducer and side branch were tied to allow movement back and forth within the side branch. After this process, the graft was pressurised with the citrated horse blood to 120 mm/Hg. During this pressurisation process, the delivery catheter was deliberately pushed into the main body of the Gelweave graft, i.e. it was forced onto the graft body wall. The force used to push the delivery catheter into the graft wall far exceeded that which a surgeon would use in the operating room. The delivery catheter was pushed onto the graft body wall 10 times over a 2 minute period. This is again in excess of what would be undertaken in the operating room during this procedure. Any blood lost from the graft due to this manual action of the delivery catheter was collected on a pre-weighed absorbent tissue. This was reweighed after the test and the total weight of blood lost from the graft calculated. The results have shown that the insertion of a 26 F endovascular delivery catheter through a 10mm side branch of a standard Gelweave graft does not alter the sealing properties of the graft i.e. does not cause damage to the structure of the graft, which would result in blood leakage.

Clinical Information: No clinical testing has been undertaken, however a comprehensive review of the literature in relation to clinical use of standard branched polyester vascular grafts in relation to performance of debranching and associated hybrid procedures is provided. These procedures are considered standard clinical practice in light of current endovascular procedures and allow surgeons to undertake repair of aortic vessels and aneurysm in either a single or two-stage procedure.

Debranching and hybrid procedures are considered an alternative treatment in the light of current endovascular procedures as they allow the surgeon to undertake repair of aortic vessels and aortic aneurysms in a less invasive approach; the gold standard of aortic arch aneurysm and thoracoabdominal aneurysm, still remains conventional open surgical repair. Since open surgical repair is a rather invasive approach and the surgical insult is often intolerable for high risk elderly patients, other alternative treatments options have emerged. As discussed, these new treatment options include hybrid procedures and also branched endovascular stent grafts.

Conclusion: In conclusion, the Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers are substantially equivalent to the predicate devices in commercial distribution and results of non-clinical tests and supporting information from the literature demonstrates that the devices continue to be safe, effective, and perform as well as the predicate devices.

Substantial Equivalence:
The Vascutek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers are substantially equivalent in overall intended use, design and materials, performance, principles of operation and technology to the predicate devices. This is shown comprehensively in Table 2, Section 10 of this pre-market notification.

There are no changes to the Vasculek Gelweave™ branched vascular grafts and Gelweave Siena™ vascular grafts with and without radiopaque markers other than the request for an expanded indication.

.....Karen Klein.....
Signature

.....2-6-09.....
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Vascutek, Ltd.
c/o Ms. Karen Kelso
Regulatory Affairs Manager
Newmains Avenue
Inchinnan Industrial Estate
Renfrewshire, Scotland
PA4 9RR, United Kingdom

Re: K090987
Trade Nmae: Vascutek Gelweave™ branched vascular grafts and
Gelweave Siena™ vascular grafts with and without radiopaque markers
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II (two)
Product Code: DSY
Dated: June 2, 2009
Received: June 9, 2009

Dear Ms. Kelso:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 09.0987

Device Name: Vascutek Gelweave™ Branched Vascular Grafts including Gelweave Siena™ Vascular Grafts with and without Radioapaque Markers

Indications For Use:

Gelweave™ branched vascular grafts:
"*Repair or replacement of damaged and diseased vessels of the abdomen and thoracic aorta in cases of aneurysm, dissection or coarctation*".

Gelweave Siena™ vascular grafts with and without radiopaque markers:
"*Repair or replacement of damaged and diseased vessels of the thoracic aorta in cases of aneurysm, dissection or coarctation*".

"*Gelweave™ branched vascular grafts, including Siena™ grafts can also be used for debranching i.e. reconstruction of the aortic vessels and associated Hybrid procedures*".

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090987