2 510(k) Summary

Date Prepared: January 25, 2008

JAN 30 2008

Submitter's Name / Contact Person

Manufacturer
GRAFTcath, Inc.
6545 City West Parkway
Eden Prairie, MN 55344

Contact Person
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General Information

Trade Name	HeRO vascular access device
Common / Usual Name	Hemodialysis vascular access device
Classification Name	870.3460 Vascular graft prosthesis, Class II
	876.5540 Catheter, hemodialysis, implant, Class III
Predicate Devices	K052964 Boston Scientific Exxcel Soft ePTFE graft
	K032900 Edwards Lifespan ePTFE graft
	Bard Access Systems Hickman Chronic Dialysis Catheter

Device Description

The HeRO device is a non-autogenous (i.e., synthetic) vascular access composed of four components: a catheter component, a pre-connected graft assembly, a crimp ring, and a sleeve. The catheter component is made of radiopaque silicone and contains reinforcing filaments that impart kink and crush resistance. The catheter is provided in two different lengths (referred to as left side and right side) to accommodate anatomical variations. During surgery, the catheter length is sized to fit the patient by peeling back the nylon filament and cutting the catheter. The pre-connected graft assembly is a conventional ePTFE hemodialysis graft that has been attached to a titanium connector. The titanium crimp ring is used during surgery to secure the catheter to the graft assembly. The silicone sleeve is placed during surgery to impart kink resistance of the catheter at the connector and to cover the metal crimp ring in silicone.

Additionally, a reusable stainless steel crimp tool is provided to compress the crimp ring for securing the catheter component to the graft assembly during surgery. The crimp tool is provided non-sterile and is steam sterilized before each use.

Intended Use

The HeRO device is intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have exhausted peripheral venous access sites suitable for fistulas or grafts.

Indications for Use

The HeRO vascular access device is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the K/DOQI guidelines[1] as patients who:

- Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
- Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography.
- Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography.
- Have a compromised central venous system or central venous stenosis (CVS) as determined by history of previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling) or venography.
- Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. K/DOQI guidelines recommend a minimum Kt/V of 1.4.[2]

Substantial Equivalence Comparison

The HeRO device is substantially similar to legally marketed 510(k)-cleared devices in intended use, principles of use, composition, sizes, packaging, and sterility. The technological differences between HeRO and the predicate devices include use of a connector to combine the graft assembly and catheter component, use of imbedded nylon and nitinol reinforcements in the catheter component to impart kink and crush resistance, and a larger catheter ID and OD.

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[1] National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Vascular Access, 2000. Am. J. Kidney Disease 37:S137-S181, 2001 (suppl 1).

[2] 2006 "K/DOQI – Clinical Practice Guidelines for Hemodialysis Adequacy Guideline 4." Minimally Adequate Hemodialysis.

Results of design verification and validation testing demonstrate that the HeRO is as safe as the predicate devices and reliably maintains long-term vascular access for hemodialysis. The risk assessment results, together with the results of design verification and validation testing presented in this submission, confirm that the HeRO device raises no new questions of safety or effectiveness compared to the predicate devices. The HeRO device has, therefore, been shown to be substantially equivalent to legally marketed devices for the purpose of 510(k) clearance.

Summary of Non-Clinical Performance Data

In vitro performance testing and ISO 10993 biocompatibility evaluations were conducted on the HeRO device. Bench tests included catheter burst strength, connection leakage, water entry pressure, device connection strength, crush resistance (catheter and marker band), catheter stiffness, catheter tensile strength and elongation, catheter fatigue testing (flex fatigue, 180 degree and V-bend), and kink resistance. All testing demonstrated that the HeRO device met its acceptance criteria.

Summary of Clinical Performance Data

Safety and performance of the HeRO device was clinically evaluated. Thirty six (36) catheter-dependent subjects (catheter arm) and 50 graft subjects (graft arm) were treated with the HeRO device for a total of 86 patients with a combined average follow-up of 10 months. The rates and types of serious adverse events reported were comparable to catheter and graft literature for the patient population studied and no new types of serious adverse events were observed. Device-related bacteremia rates were significantly lower than reported in catheter literature. Patency rates, device flow rates, and adequacy of dialysis were not significantly different from graft literature reports and significantly better than catheter literature reports. The study results demonstrate that the HeRO device is comparable to the predicate devices in materials and in bench and clinical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

GRAFTcath, Inc.
C/O Dr. Laurie E. Lynch, Ph.D.
General Manager and Vice President of R&D, Operations and RA/QA
6545 City West Parkway
Eden Prairie, MN 55344

Re: K071778
HeRO (Hemodialysis Reliable Outflow) Vascular Access Device (formerly GRAFTcath Vascular Access System [GVAS]
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY, LJS, MSD
Dated: December 11, 2007
Received: December 14, 2007

Dear Dr. Lynch:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Donna R. Vorhees

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): K071778

Device Name: HeRO Vascular Access Device

Indications For Use: The HeRO vascular access device indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the K/DOQI guidelines as patients who:

- Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
- Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
- Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography.
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vodnoy

vision Sign-Off)
vision of Cardiovascular Devices

Number K071778