K121532

510(k) Summary
(per 21 CFR 807.87(h))

JUN 22 2012

Common/Usual Name:	Vascular Graft Prosthesis
Product Trade Name:	HeRO® Graft
Classification Name:	21 CFR 870.3450; Vascular graft prosthesis; Class II; DSY, LJS, MSD, Cardiology
Predicate Device:	K071778, K091491 HeRO™ Vascular Access Device K120006 HeRO® Graft
Manufacturer:	Hemosphere, Inc. 6545 City West Parkway Eden Prairie, MN 55344
Contact:	Laurie E. Lynch, Ph.D. Director QA/RA/R&D
Date Prepared:	May 11, 2012

Device Description:

The HeRO Graft is a non-autogenous (i.e., synthetic) vascular graft prosthesis composed of three components: Arterial Graft Component, Venous Outflow Component and Accessory Component Kit. The Venous Outflow Component is made of radiopaque silicone and contains reinforcing braided filaments that impart kink and crush resistance. During surgery, the Venous Outflow Component is sized to fit the patient by cutting it to the proper length and sliding it over the barbs of the connector on the Arterial Graft Component. The Arterial Graft Component is a conventional ePTFE hemodialysis graft that has been attached to a titanium connector. The Accessory Component Kit (a convenience kit) contains instruments that assist in the implantation of the HeRO Graft.

Intended Use:

The HeRO Graft 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 Graft 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 KDOQI 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 (e.g. fistula/graft salvage).
- 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 or 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. KDOQI guidelines recommend a minimum Kt/V of 1.4.[2]

Substantial Equivalence Comparison:

The predicate device is the GRAFTcath, Inc. HeRO Vascular Access Device, K071778, K091491 and K120006. The company name has been changed from GRAFTcath, Inc. to Hemosphere, Inc. and the product name has been changed from HeRO Vascular Access Device to HeRO Graft.

Results of design verification testing demonstrate that the device system as modified is as safe as the predicate device. The risk assessment results, together with the results of design verification testing presented in this submission, confirm that the HeRO Graft, as modified, raises no new questions of safety or effectiveness compared to the predicate device. The HeRO Graft has been shown to be substantially equivalent to the legally marketed device for the purpose of 510(k) clearance.

Summary of Non-Clinical & Clinical Performance Data:

No changes were made to the previously cleared packaging verification and sterilization validation. Additional clinical performance data was not required to support the modification of the device.

---

[1] Vascular Access Work Group. National Kidney Foundation KDOQI clinical practice guidelines for vascular access. Guideline 1: patient preparation for permanent hemodialysis access. *Am J Kidney Dis* 2006;48(1Suppl1):S188-91.
[2] Hemodialysis Adequacy 2006 Work Group. National Kidney Foundation KDOQI clinical practice guidelines for hemodialysis adequacy, update 2006. *Am J Kidney Dis* 2006;48(Suppl 1):S2-S90.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Hemosphere, Inc.
c/o Laurie E. Lynch, Ph.D.
Director, QA/RA/R&D
6545 City West Parkway
Eden Prairie, MN 55344

JUN 22 2012

Re: K121532
Trade/Device Name: HeRO® Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: May 23, 2012
Received: May 24, 2012

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. 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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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 Small Manufacturers, International and Consumer Assistance 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 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 STATEMENT

Current 510(k) Number: K121532

Device Name:

HeRO® Graft

Indications for Use:

The HeRO® Graft 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 KDOQI 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 (e.g. fistula/graft salvage).
- 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 or 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. KDOQI guidelines recommend a minimum Kt/V of 1.4.[2]

[1]Vascular Access Work Group. National Kidney Foundation KDOQI clinical practice guidelines for vascular access. Guideline 1: patient preparation for permanent hemodialysis access. *Am J Kidney Dis* 2006;48(1Suppl1):S188-91.

[2]Hemodialysis Adequacy 2006 Work Group. National Kidney Foundation KDOQI clinical practice guidelines for hemodialysis adequacy, update 2006. *Am J Kidney Dis* 2006;48(Suppl 1):S2-S90.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121532