K091191

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

JUL 31 2009

Common/Usual Name:	Vascular access device
Product Trade Name:	HeRO™ Vascular Access Device
Classification Name:	21 CFR 870.3450; Vascular access prosthesis; Class II; DSY, LJS, MSD, Cardiology
Predicate Device:	K071778, HeRO™ Vascular Access Device
Manufacturer:	Hemosphere, Inc. 6545 City West Parkway Eden Prairie, MN 55344
Contact:	W. Allen Putnam Regulatory Consultant
Date Prepared:	May 18, 2009

Device Description:

The HeRO™ Vascular Access Device is a non-autogenous (i.e., synthetic) vascular access device composed of three components: HeRO™ Arterial Graft Component, HeRO™ Venous Outflow Component and HeRO™ Accessory Component Kit. The HeRO™ Venous Outflow Component is made of radiopaque silicone and contains reinforcing braided filaments that impart kink and crush resistance. During surgery, the 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 graft component. The HeRO™ Arterial Graft Component is a conventional ePTFE hemodialysis graft that has been attached to a titanium connector. The HeRO™ Accessory Component Kit (a convenience kit) contains tools that assist in the implantation of the HeRO™ Vascular Access Device.

Intended Use:

The HeRO™ Vascular Access 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 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. K/DOQI 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. The company name has been changed from GRAFTcath to Hemosphere, Inc.

Results of design verification and validation 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 and validation testing presented in this submission, confirm that the HeRO™ Vascular Access Device, as modified, raises no new questions of safety or effectiveness compared to the predicate device. The HeRO™ Vascular Access Device 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:

Packaging verification and sterilization validation have been conducted and all testing demonstrated that the HeRO™ Vascular Access Device met its acceptance criteria.

Additional clinical performance data was not required to support the modification of the device.

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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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2009

Hemosphere, Inc.
c/o Mr. W. Allen Putnam
Regulatory Consultant
6545 City West Parkway
Eden Prairie, MN 55344

Re: K091491
Trade Name: HeRO™ (Hemodialysis Reliable Outflow) Vascular Access Device
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY, LJS, MSD
Dated: June 29, 2009
Received: July 1, 2009

Dear Mr. Putnam:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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,

M. J. Hillebrenner

for 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: K091491

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HeRO™ Vascular Access Device

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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)

M. J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091491