510(k) Summary
FlowMedica, Inc.
Be*neph*it® Infusion Systems

OCT 29 2008

510(k) Notification: K 082163

GENERAL INFORMATION

Manufacturer:

FlowMedica, Inc.
46563 Fremont Blvd
Fremont, CA 94538 USA
Tel: (510) 252-9500
Fax: (510) 252-9515

Contact Person:

Jeff Elkins
President & CEO

Date Prepared:

Monday, July 28, 2008

DEVICE DESCRIPTION

The Be*neph*it® family of infusion systems comprises the Be*neph*it® CV, Be*neph*it® PV, Be*neph*it® PVMini, Be*neph*it® PVSolo, and Be*neph*it® XT systems. Each system includes a bifurcated infusion catheter and a vascular introducer sheath with dilator.

Classification:

Continuous flush catheter, 21 CFR 870.1210, class II

Catheter introducer, 21 CFR 870.1340, class II

Trade Name:

FlowMedica Be*neph*it® CV Infusion System

FlowMedica Be*neph*it® PV Infusion System

FlowMedica Be*neph*it® PVMini Infusion System

FlowMedica Be*neph*it® PVSolo Infusion System

FlowMedica Be*neph*it® XT Infusion System

Generic/common name:

Continuous flush catheter

Catheter introducer

PREDICATE DEVICES

The FlowMedica Be*neph*it® Infusion Systems, each being a legally marketed device per 21 CFR 807.92(a)(3), serve as their own predicates. Reference original 510(k) submissions K033569 (cleared January 13, 2004) and K050205 (cleared March 4, 2005).

INTENDED USE

The FlowMedica Be*neph*it® Infusion Systems are intended to facilitate targeted renal therapy, or TRT®, the delivery of physician-specified agents to the kidneys via the renal arteries. The Be*neph*it® Infusion Systems are indicated for use in patients undergoing medical, interventional, or surgical procedures, where the procedure carries an elevated risk of iatrogenic kidney injury for the patient. The Be*neph*it® Infusion Systems are also indicated to facilitate TRT® in patients who have demonstrated symptoms of acute kidney injury, and in whom arterial catheterization for TRT® is feasible.

PRODUCT DESCRIPTIONS

Each Be*neph*it® Infusion System consists of a bifurcated infusion catheter and a vascular introducer sheath with dilator. The bifurcated infusion catheter in each of the Be*neph*it® systems is a single-lumen infusion catheter with a bifurcated distal end that allows access to two locations (e.g., two renal arteries) for infusion simultaneously. Each system's introducer sheath is a PTFE-lined, coil reinforced polymer sheath with matching radiopaque dilator.

The Be*neph*it® CV system comprises a 2.4 Fr. bifurcated infusion catheter, utilizing a nitinol hypo tube shaft, and an 8 Fr. compatible introducer sheath with a unique Y-hub design. The Y-hub allows for introduction of the bifurcated infusion catheter and another interventional vascular device (up to 6 Fr. OD) simultaneously. This allows for targeted renal therapy (TRT) to be performed in conjunction with another interventional procedure through a single vascular access.

The Be*neph*it® PV, PVMini, PVSolo, and XT systems comprise a 4.8 Fr. bifurcated catheter utilizing a braid reinforced polymer shaft and a 5 Fr. compatible introducer sheath with a standard single hemostasis valve configuration. These systems provide a smaller vascular access to allow stand-alone TRT procedures or TRT in conjunction with non-interventional procedures (e.g., open surgery), or they may be used in conjunction with other interventional procedures via separate vascular access. In the case of the PVSolo uniquely, only a single infusion branch is active for infusion, allowing for TRT to a single renal artery when this is desired.

SUBSTANTIAL EQUIVALENCE

The Be*neph*it® systems covered in this submission are identical in design, materials, processing, and technological characteristics as their predicate devices, and as such are substantially equivalent in those regards. The proposed change in this submission is in the indications for use only. The change in label indications reflects specific settings for

the devices but does not alter their intended use, which is to provide targeted renal therapy, or TRT®. Because the intended use of the devices is not being changed, they are deemed substantially equivalent to their predicate devices.

SUPPORT FOR NEW INDICATION & SUBSTANTIAL EQUIVALENCE

An evaluation of data gained through normal post-production monitoring and from a FlowMedica-sponsored post-market customer preference study provides support for the new indication proposed. These data show that the Be*neph*it devices perform as intended, and are safe and effective for their intended use and for the new label indication as proposed. Thus the Be*neph*it devices with the proposed label indication change are substantially equivalent to the predicate devices.

SUMMARY

The Be*neph*it® CV, PV, PVMini, PVSolo, and XT Infusion Systems with modified indications for use as proposed here are substantially equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2008

FlowMedica, Inc.
c/o Mr. Jeff Elkins
President & CEO
46563 Fremont Blvd.
Fremont, CA 94538

Re: K082163
FlowMedica Be*neph*it® CV Infusion System, FlowMedica Be*neph*it® PV Infusion System, FlowMedica Be*neph*it® PVMini Infusion System, FlowMedica Be*neph*it® PVSolo Infusion System, FlowMedica Be*neph*it® XT Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA; DYB
Dated: July 28, 2008
Received: July 31, 2008

Dear Mr. Elkins:

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 Biometrics' (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,

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

Enclosure

FlowMedica, Inc.
46563 Fremont Blvd.
Fremont, CA 94538

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K082163

Device Name

FlowMedica Be*neph*it ® CV Infusion System

FlowMedica Be*neph*it ® PV Infusion System

FlowMedica Be*neph*it ® PVMini Infusion System

FlowMedica Be*neph*it ® PVSolo Infusion System

FlowMedica Be*neph*it ® XT Infusion System

Indications for Use:

The FlowMedica Be*neph*it® Infusion Systems are intended to facilitate targeted renal therapy, or TRT®, the delivery of physician-specified agents to the kidneys via the renal arteries. The Be*neph*it® Infusion Systems are indicated for use in patients undergoing medical, interventional, or surgical procedures, where the procedure carries an elevated risk of iatrogenic kidney injury for the patient. The Be*neph*it® Infusion Systems are also indicated to facilitate TRT® in patients who have demonstrated symptoms of acute kidney injury, and in whom arterial catheterization for TRT® is feasible.

Prescription Use X or Over-the-counter Use _____

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: K082163