JAN 1 3 2004

510(k) Summary

FlowMedica, Inc.

Bifurcated Infusion System

510(k) Notification K 033569

GENERAL INFORMATION

Manufacturer:

FlowMedica, Inc.
46563 Fremont Boulevard
Fremont, CA 94538

P: (510) 252-9500
F: (510) 252-9515

Contact Person:

Jeff Elkins
Vice President of R&D and COO

Date Prepared:

November 07, 2003

DEVICE DESCRIPTION

The FlowMedica Bifurcated Infusion System consists of the FlowMedica Bifurcated Infusion Catheter and the FlowMedica Introducer Sheath.

Classification:

Continuous Flush Catheter, 21 CFR Sec. 870.1210, Class II

Introducer, Catheter, 21 CFR Sec. 870.1340, Class II

Trade Name:

FlowMedica Bifurcated Infusion System:

FlowMedica Bifurcated Infusion Catheter

FlowMedica Introducer Sheath

Generic/Common Name:

Continuous Flush Catheter

Introducer, Catheter

PREDICATE DEVICES

FlowMedica Bifurcated Infusion Catheter:
Boston Scientific Mewissen™ Catheter (K904788)
Interventional Innovations Flower™ Infusion Catheter (K955525)
EKOS Peripheral Infusion System (K030637)
Boston Scientific Katzen™ Thrombolysis Wire (K883880)
Boston Scientific Cragg FX™ Wire (K897152).

FlowMedica Introducer Sheath:
Cook Check-Flo® Performer® Introducer (unable to determine 510[k] reference)
Cook Shuttle® SL Flexor® Tuohy-Borst Side Arm Introducer Set (unable to determine 510[k] reference)
Super Arrow-Flex® Percutaneous Sheath Introducer Set (K924607, K970229)
Terumo Pinnacle™ Destination™ Renal Guiding Sheath (K012854)

INTENDED USE

The FlowMedica Bifurcated Infusion System is intended for the infusion of physician-specified agents in the peripheral vasculature including but not limited to the renal arteries.

The FlowMedica Introducer Sheath is intended to facilitate the entry of interventional and diagnostic devices into the human vasculature.

PRODUCT DESCRIPTION

The FlowMedica Bifurcated Infusion System consists of the Bifurcated Infusion Catheter and the Introducer Sheath. It is intended for single-use only and is sterilized using ethylene oxide gas.

The Bifurcated Infusion Catheter functions by selectively delivering physician-specified agents directly to the peripheral vasculature. The Bifurcated Infusion Catheter contains a 77cm working length shaft/infusion lumen. It is bifurcated at the distal end, which is comprised of two identical metal-supported and braided polymer branches.

The Introducer Sheath provides for the introduction of two interventional devices through a single vessel access site, allowing for the introduction of the Bifurcated Infusion Catheter and the introduction of a standard coronary guiding or diagnostic catheter as may be required for a catheterization procedure. The Introducer Sheath, available in four lengths, is a polymer and metal coil reinforced sheath with two insertion ports in its integral Y hub assembly. The ports contain a hemostasis valve, designed for a 6Fr diagnostic or guiding catheter, and Touhy Borst valve used for the Bifurcated Infusion Catheter. A vessel dilator is supplied with the Introducer Sheath.

K033569

The FlowMedica Bifurcated Infusion Catheter is designed for use only with the FlowMedica Introducer Sheath. Each component is packaged separately and may be ordered and shipped separately; however, the Instructions for Use included with the Bifurcated Infusion Catheter specify exclusive usage with the FlowMedica Introducer Sheath.

SUBSTANTIAL EQUIVALENCE

The FlowMedica, Inc. Bifurcated Infusion System consists of the Bifurcated Infusion Catheter and the Introducer Sheath.

The FlowMedica Bifurcated Infusion Catheter has substantially equivalent indications for use, and/or technological characteristics as the Boston Scientific Mewissen™ Catheter (K904788), the Interventional Innovations Flower™ Infusion Catheter (K955525), the EKOS Peripheral Infusion System (K030637), the Boston Scientific Katzen™ Thrombolysis Wire (K883880), and the Boston Scientific Cragg FX™ Wire (K897152). Any differences in the technological characteristics do not raise any new issues of safety or efficacy. Comparative bench testing demonstrates that the performance and safety of the FlowMedica Bifurcated Infusion Catheter is equivalent to that of the predicate devices. Thus, it is substantially equivalent to the predicate devices.

The FlowMedica Introducer Sheath has substantially equivalent indications for use and and/or technological characteristics as the Cook Check-Flo® Performer® Introducer (unable to determine 510[k] reference), the Cook Shuttle® SL Flexor® Tuohy-Borst Side Arm Introducer Set (unable to determine 510[k] reference), the Super Arrow-Flex® Percutaneous Sheath Introducer Set (K924607 and K970229), and the Terumo Pinnacle™ Destination™ Renal Guiding Sheath (K012854). Any differences in the technological characteristics do not raise any new issues of safety or efficacy. Comparative bench testing demonstrates that the performance and safety of the FlowMedica Introducer Sheath is equivalent to that of the predicate devices. Thus, it is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The following testing has been conducted. The results of the testing demonstrate that the FlowMedica, Inc. Bifurcated Infusion System performs as designed, is suitable for its intended use, and that it is substantially equivalent to the predicate devices:

- Design Verification Testing
- Biocompatibility Testing
- Animal Testing
- Predicate Device Comparative Testing

SUMMARY

The FlowMedica Bifurcated Infusion Catheter and the FlowMedica Introducer Sheath (the Bifurcated Infusion System) are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2004

FlowMedica, Inc.
c/o Mr. Jeff Elkins
Vice President R&D and COO
46563 Fremont Boulevard
Fremont, CA 94538

Re: K033569
Trade/Device Name: FlowMedica Bifurcated Infusion System
Regulation Numbers: 21 CFR 870.1250; 21 CFR 870.1340
Regulation Names: Continuous Flush Catheter; Catheter Introducer
Regulatory Class: Class II
Product Codes: KRA; DYB
Dated: November 11, 2003
Received: November 12, 2003

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 Office of Compliance at (301) 594-4586. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Ashley B Boam

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

510(k) Number (if known): K033569

Device Name: FlowMedica Bifurcated Infusion System

Indications For Use: Infusion of physician-specified agents in the peripheral vasculature including but not limited to the renal arteries.

The FlowMedica Introducer Sheath is intended to facilitate the entry of interventional and diagnostic devices into the human vasculature.

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

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(Division Sign-off)
Division of Cardiovascular Devices

510(K) Number K033569 (SM. K)