K101754

Greatbatch Medical

NOV 26 2010

510(k) Summary

5.1 Applicant Information

Submitter's Name:	Greatbatch Medical
Address:	2300 Berkshire Lane North Minneapolis, MN 55441
Establishment Registration No.	2183787
Contact Person:	Kristi Fox Regulator Affairs Specialist kfox@greatbatchmedical.com 763-951-8205 (phone) (763) 559-0148 (fax)
Sterilization Facility:	Steris, Inc. 380 90th Avenue Northwest Minneapolis, MN 55433 (763) 786-2929 (phone) (763) 786-8199 (fax) Establishment Registration No. 2183744

5.2 Device Information

Trade Name: MobiCath™ Bi-Directional Guiding Sheath
Classification Name: Introducer, Catheter
Product Code: DYB
Regulation: Class II 21 CFR 870.1340
Panel: Cardiovascular

5.3 Device Description

The MobiCath™ Bidirectional Guiding Sheath is an 8.5 French, flexible tipped percutaneous catheter introducer (or guiding sheath) designed for gaining access to the coronary systems. The device features adjustable tip geometry that allows deflection of the distal portion of the device bi-directionally 150°. This feature provides steerability to facilitate the delivery of therapeutic devices into the heart including the left atrium, using minimally invasive techniques. The sheath is fitted with a hemostatic valve which minimizes blood loss and air intake by providing hemostasis sealing to venous pressures as well as reduce dilator insertion and removal force. The sheath is also equipped with a sideport attached to a segment of extension tubing terminating in a 3-way stopcock. The sheath and dilator contain radiopaque material for visualization under fluoroscopy.

5.4 Indications for Use

The Bidirectional Guiding Sheath is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

5.5 Predicate Device Comparison / Technological Characteristics

The MobiCath™ Bidirectional Guiding Sheath has the same indication for use, technological characteristics and principles of operation as the market cleared St. Jude Medical Agilis™ NxT Steerable Introducer (*K083402*). In addition, functional characteristics of the MobiCath™ Bidirectional Guiding Sheath are substantially equivalent to the Agilis NxT Steerable Introducer and the market cleared Enpath Medical Steerable Sheath (*K061119*) including materials, dimensions, and method of construction. Where dimensional and material differences exist between the proposed device and the predicate devices, performance and biocompatibility testing were performed to demonstrate that these differences do not raise questions of safety or efficacy.

5.6 Summary of Testing

The MobiCath™ Bidirectional Guiding Sheath passed all verification specification criteria for dimensional, strength, functional, packaging, sterilization, biocompatibility and shelf life tests. Test results confirm the device performs as intended without raising additional questions of safety and efficacy when compared to the predicates. Given the similar technological characteristics and principles of operation of the MobiCath™ Bidirectional Guiding Sheath and the predicate devices, it was determined that no animal or clinical study was deemed necessary.

5.7 Statement of Equivalence

The MobiCath™ Bidirectional Guiding Sheath has the same indication for use, technological characteristics and principles of operation as the market cleared St. Jude Medical Agilis™ NxT Steerable Introducer (*K083402*). In addition, the technological characteristics and principles of operation of the MobiCath™ Bidirectional Guiding Sheath are similar the market cleared Enpath Medical Steerable Sheath (*K061119*). Therefore, the MobiCath™ Bidirectional Guiding Sheath is substantially equivalent to the previously cleared St. Jude Medical Agilis™ NxT Steerable Introducer (*K083402*) and Enpath Medical Steerable Sheath (*K061119*).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 23, 2015

Greatbatch Medical
Ms. Kristi Fox
Regulatory Affairs Specialist
2300 Berkshire Lane North
Minneapolis, Minnesota 55441

Re: K101784
Trade/Device Name: MobiCath Bi-Directional Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 26, 2010
Received: November 26, 2010

Dear Ms. Fox:

This letter corrects our substantially equivalent letter of November 26, 2010.

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

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 Part 801), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Cynthia Chang -S

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

510(k) Number (if known): K101784

NOV 26 2010

Device Name: MobiCath Bi-Directional Guiding Sheath

Indications for Use:

The Bidirectional Guiding Sheath is intended for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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)

(Division Sign Off)
Division of Cardiovascular Devices

510(k) Number K101784

1 of 1