K102540

Greatbatch Medical

NOV 16 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: PTFE Peelable Introducer
Classification Name: Introducer, Catheter
Product Code: DYB
Regulation: Class II 21 CFR 870.1340
Panel: Cardiovascular

5.3 Device Description

The Greatbatch Medical PTFE Peelable Introducer Kit consists of a disposable needle, a disposable syringe, a guidewire, and a peelable introducer set consisting of a dilator and sheath with integrated proximal handles. The introducer is available in various lengths in 3.5F through 16.5F. The dilator is designed to be delivered over a guidewire.

The PTFE Peelable Introducer sheath has a "peel-away" feature which allows the user to remove the sheath without removing the inserted catheter or pacing lead. The PTFE Peelable Introducer is provided sterile and is intended for single use. The device is not intended for sterilization by the user.

5.4 Indications for Use

The PTFE Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

5.5 Predicate Device Comparison / Technological Characteristics

The PTFE Peelable Introducer Kit has the same indication for use, technological characteristics and principles of operation as the market cleared Greatbatch Medical PTFE Peelable Introducer Kit (*K093023*). In addition, functional characteristics of the PTFE Peelable Introducer are substantially equivalent to the currently marketed device (*K093023*) including materials and method of construction. Where dimensional differences exist between the proposed device and the predicate device, performance testing was performed to demonstrate that these differences do not raise questions of safety or efficacy.

5.6 Summary of Testing

Testing for this device was performed to verify that the device continues to function in a safe and effective manner. The performance testing included the device specifications, functional and dimensional testing of the PTFE Peelable Introducer and other testing as applicable to the device. Test results verify that the device performs per specification requirements and is equivalent to the predicate device without creating additional risk to the patient or user. The following tests were performed on the PTFE Peelable Introducer:

Test	Result
Sheath Compatibility with Dilator	Pass
Initial Handle Break Force, Sheath	Pass
Peel Force	Pass
Peelability	Pass
Sheath/Tube Handle Integrity	Pass
Dilator Hub/Tube Tensile Force	Pass
Handle ID (min)	Pass
Dilator Hub ID	Pass
Tip ID	Pass
Flat on Tip	Pass
Tip Angle	Pass
Length	Pass

5.7 Statement of Equivalence

The PTFE Peelable Introducer has the same indication for use, principles of operation, and technological and functional characteristics as the market cleared Greatbatch Medical PTFE Peelable Introducer (*K093023*). The testing performed confirms that the PTFE Peelable Introducer will perform as intended. Therefore the PTFE Peelable Introducer is substantially equivalent to the previously cleared Greatbatch Medical PTFE Peelable Introducer (*K093023*).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Kristi Fox
Regulatory Affairs Specialist
Greatbatch Medical
2300 Berkshire Lane North
Minneapolis, MN 55441

NOV 16 2010

Re: K102540
Trade/Device Name: PTFE Peelable Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 15, 2010
Received: November 3, 2010

Dear Ms. Fox:

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 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. 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,

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

Indications for Use Statement

510(k) Number (if known): K102540

Device Name: PTFE Peelable Introducer

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Indications for Use:

The PTFE Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

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)

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

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