K093232

Greatbatch Medical

510(K) Summary

MAR 15 2010

5.1 Applicant Information

Submitter's Name:	Greatbatch Medical
Address:	2300 Berkshire Lane North Minneapolis, MN 55441
Establishment Registration No:	2183787
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Sterilization Facility:	Steris, Inc. 380 90th Avenue Northwest Minneapolis, MN 55433 Tel: 763-786-2929 Fax: 763-786-8199 Establishment Registration No: 2183744

5.2 Device Information

Trade Name:	OptiSeal™ Valved 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 OptiSeal Valved PTFE Peelable Introducer, available in non-sideport and sideport configurations, is a small diameter tubular shaped device with integrated proximal handles. Both configurations of the OptiSeal Valved PTFE Peelable Introducer are designed to provide a relatively atraumatic method for insertion of catheters and pacemaker leads into the venous system while providing hemostatic sealing to venous pressures. Both introducer configurations peel away after use allowing the user to remove the introducer without removing the inserted catheter or pacing lead. The sideport configuration of the OptiSeal Valved Peelable Introducer is equipped with a sideport attached to a segment of extension tubing terminating in a 3-way stopcock.

The OptiSeal Valved PTFE Peelable Introducer is packaged in sterile convenience kits containing a Valved PTFE Peelable Introducer, a thin-wall needle, a disposable syringe, and a flexible guidewire. The convenience kits are packaged five (5) per box.

5.4 Indications for Use

The OptiSeal™ Valved PTFE Peelable 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 OptiSeal Valved PTFE Peelable Introducer, available in both non-sideport and sideport configurations, is a modification of the previously cleared non-sideport ViaSeal Valved Peelable Introducers (*K063182*). The OptiSeal Valved PTFE Peelable Introducer configurations covered by this submission are identical in function, mechanism of action and intended use as the predicate non-sideport ViaSeal Valved Peelable Introducers (*K063182*). In addition, the OptiSeal Valved PTFE Peelable Introducer with sideport shares a similar intended use, with respect to use in the venous system, and mechanism of action as the sideported Merit Prelude Sheath Introducer (*K070159*).

5.6 Summary of Testing

The OptiSeal Valved PTFE Peelable Introducer 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 predicate. Given the limited scope of the modifications incorporated to create the OptiSeal Valved PTFE Peelable Introducer and identical intended use,no animal or clinical data was deemed necessary.

5.7 Statement of Equivalence

The Greatbatch Medical OptiSeal Valved PTFE Peelable Introducer has identical indications for use, technological characteristics and principles of operation as the market cleared ViaSeal Valved Peelable Introducers (*K063182*). In addition, the OptiSeal Valved PTFE Peelable Introducer with sideport shares a similar intended use, with respect to use in the venous system, and mechanism of action as the Merit Prelude Sheath Introducer (*K070159*). The differences between this device and its predicate devices do not raise new questions of safety or efficacy. Therefore, the OptiSeal Valved PTFE Peelable Introducer is substantially equivalent to the previously cleared ViaSeal Valved Peelable Introducers (*K063182*) and Merit Prelude Sheath Introducer (*K070159*).

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

Greatbatch Medical
c/o Ms. Shannon Springer
Principal Regulatory Affairs Specialist
2300 Bershire Lane North
Minneapolis, MN 55441

MAR 15 2010

Re: K093232
Trade Name: OptiSeal™ Valved PTFE Peelable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II (two)
Product Code: DYB
Dated: March 8, 2010
Received: March 9, 2010

Dear Ms. Springer:

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 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 (240) 276-3150 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

Enclosure

Indications for Use Statement

510(k) Number (if known): K093232

Device Name: OptiSeal Valved PTFE Peelable Introducer

Indications for Use:

The OptiSeal™ Valved 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. Vochner

(Division Sign-Off)
Division of Cardiovascular Devices

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