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510(k) Number: K093414

Date Prepared October 29, 2009

Submitter Information

MAR - 1 2010

Submitter's Name: Smiths Medical ASD, Inc.
Address: 1265 Grey Fox Road
St. Paul, MN 55112

Establishment Registration: 2183502

Contact Person: Rachelle Parsons, RAC
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Device Information

Trade Name:	PORT-A-CATH® POWER P.A.C. Implantable Venous Access Systems
Common Name:	Subcutaneously Implanted Intravascular Infusion Port and Catheter
Classification Name:	Port and Catheter, Implanted, Subcutaneous, Intravascular
Product Code:	LJT
Regulation:	21 CFR §880.5965
Trade Name:	PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems
Common Name:	Subcutaneously Implanted Intravascular Infusion Port and Catheter
Classification Name:	Port and Catheter, Implanted, Subcutaneous, Intravascular
Product Code:	LJT
Regulation:	21 CFR §880.5965

Predicate Device(s)

The predicate devices are the above currently marketed devices. The reference 510(k) numbers for these devices are as follows:

Device	510(k)
PORT-A-CATH® POWER P.A.C. Implantable Venous Access Systems PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems	K070116 and K072657

Device Descriptions

PORT-A-CATH®, PORT-A-CATH® II POWER P.A.C. line of Access Ports

The PORT-A-CATH® POWER P.A.C and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems are totally implantable venous access systems designed to permit repeated access to the venous system for the parenteral delivery of medications, fluids, nutritional solutions, and for the sampling of venous blood. When used with a power indicated Huber needle, the PORT-A-CATH® POWER P.A.C. and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems are indicated for power injection of contrast media.

The PORT-A-CATH® POWER P.A.C. and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems can be placed in the chest or arm, are supplied sterile, are non-pyrogenic and intended for single patient use only. The PORT-A-CATH® POWER P.A.C and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems consists of a portal with one or two self-sealing septa, and catheter connector that are assembled during implantation. The systems are offered in either a kit or a tray configuration.

Intended Use/Indications for Use

The PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

When used with a GRIPPER PLUS® POWER P.A.C. Safety Huber Needle or other power injectable Huber needle, the PORT-A-CATH® POWER P.A.C. implantable venous access systems are indicated for power injection of contrast media.

510(k) Summary

Summary of Non-Clinical Testing

The non-clinical testing included assessment of the physical properties of the PORT-A-CATH® POWER P.A.C. Implantable Venous Access System and its ability to achieve its intended use. Bench testing of the device confirmed the suitability of the device for its intended use.

Biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. The device is biocompatible based on the similarity of the materials of construction to the predicate devices commercially marketed by Smiths Medical ASD, Inc.

MR safety testing was performed on selected ports in accordance with established American Society for Testing and Materials (ASTM) standards. This testing was performed to establish the safety of the listed medical devices in the MR environment. The devices selected represent the entire product line of the devices listed. Testing was performed in the presence of a 3 Tesla MR imaging device.

The devices listed were determined to be MR Conditional according to the terminology specified in the ASTM Designation F2503-05 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Summary of Clinical Testing

Human clinical studies were deemed not necessary to evaluate the safety or effectiveness of the PORT-A-CATH® POWER P.A.C. Implantable Venous Access Systems.

Statement of Equivalence

The PORT-A-CATH® POWER P.A.C. Implantable Venous Access System is substantially equivalent to the currently marketed Power PAC Implantable Venous Access System based on a comparison of the indications for use and the technological characteristics of the device.

Conclusion

The PORT-A-CATH® POWER P.A.C. Implantable Venous Access System is substantially equivalent to the currently marketed Power PAC Implantable Venous Access System based on the technological characteristics of the device. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Rachelle Parsons
Senior, Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
1265 Grey Fox Road
Saint Paul, Minnesota 55112

MAR - 1 2010

Re: K093414
Trade/Device Name: PORT –A-CACH® II POWER P.A.C. Implantable Venous Access Systems, PORT-A-CATH® POWER P.A.C. Implantable Venous Access Systems, P.A.S. Port® T2 POWDER PAC Implantable Venous Access Systems
Regulation Number: 21CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: February 17, 2010
Received: February 18, 2010

Dear Ms. Parsons:

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 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K093414

Device Name: PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems

Indications for Use:

"The PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

When used with a GRIPPER PLUS® POWER P.A.C. Safety Huber Needle or other power injectable Huber needle, the PORT-A-CATH® II POWER P.A.C. implantable venous access systems are indicated for power injection of contrast media. For power injections of contrast media, the maximum recommended infusion rate is 5 ml/sec."

Prescription Use (Per 21 CFR 801.109)	X	AND/OR	Over-The Counter Use (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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093414

Indications for Use

510(k) Number: K093414

Device Name: PORT-A-CATH® POWER P.A.C. Implantable Venous Access Systems

Indications for Use:

"The PORT-A-CATH® POWER P.A.C. Implantable Venous Access Systems are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

When used with a GRIPPER PLUS® POWER P.A.C. Safety Huber Needle or other power injectable Huber needle, the PORT-A-CATH® POWER P.A.C. implantable venous access systems are indicated for power injection of contrast media. For power injections of contrast media, the maximum recommended infusion rate is 5 ml/sec."

Prescription Use X (Per 21 CFR 801.109)	AND/OR	Over-The Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093414

Indications for Use

510(k) Number: K093414

Device Name: P.A.S. Port® T2 POWER P.A.C. Implantable Venous Access Systems

Indications for Use:

"The P.A.S Port® T2 POWER P.A.C. Implantable Venous Access Systems are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.

When used with a GRIPPER PLUS® POWER P.A.C. Safety Huber Needle or other power injectable Huber needle, the P.A.S. Port® POWER P.A.C. implantable venous access systems are indicated for power injection of contrast media. For power injections of contrast media, the maximum recommended infusion rate is 5 ml/sec."

Prescription Use (Per 21 CFR 801.109)	X	AND/OR	Over-The Counter Use (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)

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