K070116

SMITHS MEDICAL MD, INC.
510(k) Premarket Notification

PORT-A-CATH® POWER P.A.C. Implantable Venous Access System, PORT-A-CATH® II POWER P.A.C. Implantable Venous Access System, and GRIPPER PLUS® POWER P.A.C. Needle

510(k) Summary

MAY 23 2007

I. Applicant (Sponsor) Name and Address

Smiths Medical MD, Inc.

1265 Grey Fox Road

St. Paul, MN 55112

Establishment Reg. No.: 2183502

II. Contact Name and Phone

Phil Neururer

Senior Regulatory Affairs Specialist

Company Phone: (651) 628-7592

Company Fax: (651) 628-7457

III. Device Trade/Proprietary Name

Catheter/Port

PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems

Needle

GRIPPER PLUS® POWER P.A.C. needle

IV. Device Classification/Common Name/Panel

Catheter/Port

21 CFR Reference: §880.5965
21 CFR Common Name: Implanted Infusion Port
Classification: Class II
Product Code: LJT
Panel: General Hospital

Needle

21 CFR Reference: §880.5440
21 CFR Common Name: Huber Needle Intravascular Administration Set
Classification: Class II
Product Code: FPA
Review Panel: General Hospital and Personal Use

V. Identification of Predicate Device

Smiths Medical MD, Inc. believes the PORT-A-CATH® POWER P.A.C. implantable venous access system, PORT-A-CATH® II POWER P.A.C. implantable venous access system, and GRIPPER PLUS® POWER P.A.C. needle are substantially equivalent to the following devices and thus may market the devices under these equivalencies.

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510(k) Summary

Catheter/Port

Device Name/510(k) number:

PORT-A-CATH® implantable venous access system (K864446, K875276, K932095, K942024, and K060036)
PORT-A-CATH® II implantable venous access system (K932840, K942024, K962695, and K060036)
PowerPort™ Implanted Titanium Port with 8Fr. ChronoFlex® (K060812)

Needle

Device Name/510(k) number:

GRIPPER PLUS® needle (K021999)

VI. Device Description

PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems

The PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems are similar to the current PORT-A-CATH® and PORT-A-CATH® II implantable venous access systems. They both 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. However, when used with a GRIPPER PLUS® POWER P.A.C. needle, the PORT-A-CATH® 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® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems can be placed in the chest or arm.

The PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems are supplied sterile and non-pyrogenic. All PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems are designed and intended for single patient use only. A system consists of a portal with one or two self-sealing septa and a single or dual lumen catheter and is accessible by percutaneous puncture with a non-coring needle.

GRIPPER PLUS® POWER P.A.C. Needle

The GRIPPER PLUS® POWER P.A.C. needle is similar to the current GRIPPER PLUS® needle, with the addition of an added indication. Both are supplied sterile and non-pyrogenic and are intended for the administration into or withdrawal of fluids from implanted ports. In addition, they both have a passive needle stick protection feature that is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries. It does not protect against other routes of bloodborne pathogen transmission.

The difference between the two however, is when used with a PORT-A-CATH® and/or PORT-A-CATH® II POWER P.A.C. implantable venous access system; the GRIPPER PLUS® POWER P.A.C. needle is indicated for power injection of contrast media.

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510(k) Summary

VII. Intended Use of the Device

The intended use of each device has not changed from that of the predicate.

PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems

The PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems are implantable vascular access devices designed to provide long term repeated access to the vascular system.

GRIPPER PLUS® POWER P.A.C. Needle

The GRIPPER PLUS® POWER P.A.C. needle is designed for the administration into or withdrawal of fluids from implanted ports.

VIII. Indications for Use

The Indications for Use of each device has changed from that of the predicate with the addition of power injection.

PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. Implantable Venous Access Systems

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. needle, the PORT-A-CATH® and PORT-A-CATH® II POWER P.A.C. implantable venous access systems are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec.

GRIPPER PLUS® POWER P.A.C. Needle

The GRIPPER PLUS® POWER P.A.C. needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries.

When used with the PORT-A-CATH® and/or PORT-A-CATH® II POWER P.A.C. implantable venous access system, the GRIPPER PLUS® POWER P.A.C. needle is indicated for power injection of contrast media into the central venous system. The maximum recommended infusion rate is 5 ml/sec. for 19 and 20 gauge needles and 3ml/sec. for 22 gauge needles.

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PORT-A-CATH® POWER P.A.C. Implantable Venous Access System, PORT-A-CATH® II POWER P.A.C. Implantable Venous Access System, and GRIPPER PLUS® POWER P.A.C. Needle

510(k) Summary

IX. Summary of Studies

A. Functional Testing

The PORT-A-CATH® POWER P.A.C. implantable venous access system, PORT-A-CATH® II POWER P.A.C. implantable venous access system, and GRIPPER PLUS® POWER P.A.C. needle met all established acceptance criteria for performance testing and design verification testing.

Packaging and Sterilization systems are unchanged from predicate devices.

B. Clinical Studies

Clinical studies for the PORT-A-CATH® POWER P.A.C. implantable venous access system, PORT-A-CATH® II POWER P.A.C. implantable venous access system, and GRIPPER PLUS® POWER P.A.C. needle were deemed not necessary due to their similarity in materials, design and function to current Smiths Medical MD, INC. devices and other commercially available systems.

C. Conclusions Drawn from the Studies

Based upon the information provided; the PORT-A-CATH® POWER P.A.C. implantable venous access system, PORT-A-CATH® II POWER P.A.C. implantable venous access system, and GRIPPER PLUS® POWER P.A.C. needle met all acceptance criteria for performance testing and design verification testing. Therefore, these products are considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2007

Mr. Phil Neururer
Senior Regulatory Affairs Specialist
Smiths Medical MD, Incorporation
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K070116
Trade/Device Name: PORT-A-CATH and PORT –A-CATH II Power P.A.C. Implantable Venous Access Systems and Gripper Plus Power P.A.C. Needle
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT, FPA
Dated: April 18, 2007
Received: April 19, 2007

Dear Mr. Neururer:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SMITHS MEDICAL MD, INC.
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PORT-A-CATH® II POWER P.A.C. Implantable Venous Access System,
and GRIPPER PLUS® POWER P.A.C. Needle

Indications for Use

510(k) Number (if known): K070116

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. needle, the PORT-A-CATH® POWER P.A.C. implantable venous access system is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

(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: K070116

PORT-A-CATH® POWER P.A.C. Implantable Venous Access System,
PORT-A-CATH® II POWER P.A.C. Implantable Venous Access System,
and GRIPPER PLUS® POWER P.A.C. Needle

Indications for Use

510(k) Number (if known): K070116

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 system is 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. needle, the PORT-A-CATH® II POWER P.A.C. implantable venous access system is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

(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 K070116

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510(k) Premarket Notification

PORT-A-CATH® POWER P.A.C. Implantable Venous Access System,
PORT-A-CATH® II POWER P.A.C. Implantable Venous Access System,
and GRIPPER PLUS® POWER P.A.C. Needle

Indications for Use

510(k) Number (if known): K070116

Device Name: GRIPPER PLUS™ POWER P.A.C. Needle

Indications for Use:

"The GRIPPER PLUS® POWER P.A.C. needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries.

When used with the PORT-A-CATH® POWER P.A.C. and POWER PORT-A-CATH® II POWER P.A.C. implantable venous access systems, the GRIPPER PLUS® POWER P.A.C. needle is also indicated for power injection of contrast media into the central venous system. The maximum recommended infusion rate is 5 ml/sec. for 19 and 20 gauge needles and 3ml/sec. for 22 gauge needles."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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