K032044

JUL 10 2003

Section 6

510(k) Summary
X-Port *duo*™ Implanted Port

510(k) Summary of Safety and Effectiveness Information
21CFR 807.92

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5439
Fax Number:	(801) 595-5425
Contact Person:	John Knorpp
Date of Preparation:	1 July 2003

6.2 Device Name

Device Name:	Plastic Dual Port
Trade Name:	X-Port *duo*™ Port
Common/Usual Name:	Plastic Subcutaneous Port & Catheter
Classification Name:	80LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965 – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II
Classification Panel:	General Hospital

6.3 Predicate Device Name

Device Name:	Plastic Attachable Dual Port
Trade Name:	MRI® Dual Port
Common/Usual Name:	Plastic Subcutaneous Port & Catheter
Classification Name:	80LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965 – Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II
Premarket Notification:	K912702, concurrence date – 18 September 1991.

6.4 Device Description

Principles of Operation
There are no new operating principles. The X-Port *duo*™ port has the same basic, fundamental scientific technology as the predicate MRI® Dual port. Access to the port is made percutaneously with a non-coring needle that enters the port reservoir via the silicone rubber septum. The access path to the vascular system is provided through a catheter attached to the base of the port. The port system serves as a conduit for fluids into, and out of, the central venous system.

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Port Body

- The port body consists of an oblong shaped plastic base and top.
- The silicone septa are compressed between the port base and top.
- The port body profile incorporates smooth transitions.
- There are two suture holes adjacent to the stem and a third suture hole placed opposite the stem on the tapered nose. All suture holes are filled with silicone plugs.

Catheters, Stems and Catheter Locks

- All catheters and catheter/port connection systems used on the X-Port *duo* port are previously qualified legally marketed configurations covered by the predicate device.

6.5 Intended Use

The X-Port *duo*™ Implanted Port is a totally implantable vascular access device designed to provide long term repeated access to the vascular system.

This is the identical intended use for the predicate MRI® Dual port.

6.6 Summary of Technological Characteristics in Relation to the Predicate Device

The X-Port *duo*™ port design has some minor differences from the predicate MRI® Dual port, however the basic fundamental scientific technology of the port has not changed. The primary differences include the following: Larger separate two-piece septa, a lower profile port body with smooth transitions and three silicone filled suture holes.

6.7 Nonclinical Performance Testing

The appropriate design verification tests were performed in accordance with *Guidance on 510(k) Submission for Implanted Infusion Ports*, dated October 1990. Design validation was also performed to meet the recommendations of the FDA guidance document, *Design Control Guidance for Medical Device Manufacturers*, dated March 11, 1997.

Performance data gathered in design verification and validation testing demonstrated that the X-Port *duo*™ port is substantially equivalent to the predicate MRI® Dual port and/or met predetermined acceptance criteria, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

6.8 Clinical Performance Testing

Clinical performance testing was not required.

6.9 Conclusion

Based on FDA's decision tree, the X-Port *duo*™ port is substantially equivalent to the predicate device MRI® Dual port, K912702, cleared September 18, 1991.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2003

Mr. John Knorpp
Senior Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 W. Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K032044
Trade/Device Name: BardPort®, SlimPort™ and X-Port™
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: July 1, 2003
Received: July 2, 2003

Dear Mr. Knorpp:

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 (301) 594-4618. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.2

INDICATION(S) FOR USE STATEMENT*

The BardPort®, SlimPort™ and X-Port™ Implanted Ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

Signature of 510(k) Submitter: John C. Knorpp

Printed Name of Submitter: John C. Knorpp
Senior Regulatory Affairs Specialist

Date: 6-19-03

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number: K032044

Division Sign-Off:
Office of Device Evaluation

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

510(k) Number: K032044

Prescription Use: _____ – OR – Over-The-Counter Use: _____