SEP 2 5 2002

K022983

Section 6

510(k) Summary
X-Port *isp* 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:	6 September 2002

6.2 Device Name

Device Name:	BardPort® Implanted Port
Trade Name:	X-Port *isp*™
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

6.3 Predicate Device Name

Device Name:	BardPort Implanted Port
Trade Name:	Hickman® Plastic Subcutaneous 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:	K873213, concurrence date – October 27, 1987.

6.4 Device Description

Principles of Operation
There are no new operating principles. The X-Port *isp* port relies on the same basic, fundamental scientific technology as the predicate Hickman 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.

Port Body
- The port body consists of an oval shaped plastic base and top.
- The silicone septum is compressed between the port base and top.
- The port body profile incorporates smooth transitions, a tapered nose and is intermediate sized.

- There are only two suture holes, which are adjacent to the stem and are filled with silicone plugs.

Catheters, Stems and Catheter Locks

- The catheters, stems and catheter locks used with the X-Port *isp* port are unchanged, previously qualified legally marketed devices covered by the predicate device and come in multiple French sizes.

6.5 Intended Use

The BardPort X-Port *isp* 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 Hickman port.

6.6 Summary of Technological Characteristics in Relation to the Predicate Device

6.6.1 Does the new device have the same indication statement?

Yes.

6.6.2 Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The X-Port *isp* port design has some minor differences from the predicate Hickman port, however the basic fundamental scientific technology of the port has not changed. The differences include the following: a larger septum, a lower profile intermediate size port body, two silicone filled suture holes located adjacent to the stem and a tapered nose.

6.6.3 Could the new characteristics affect safety or effectiveness?

Yes. The above features could affect safety or effectiveness of the device.

6.6.4 Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new issues of safety and effectiveness.

6.6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's *Guidance on 510(k) Submissions for Implanted Infusion Ports*, dated October 1990 was used to evaluate the device's performance.

Design validation was performed to meet the recommendations of the FDA guidance document, *Design Control Guidance for Medical Device Manufacturers*, dated March 11, 1997.

Biocompatibility requirements of *ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*, and the FDA-Modified ISO 10993 Test Profile for a long term implanted device that exhibits tissue contact, indirect blood contact and direct blood contact, were met. No materials are used in the manufacture of the subject device that have not already been cleared for similar applications by Bard Access Systems.

6.6.6 Are performance data available to assess effects of new characteristics?

Yes. Verification and validation testing was performed according to protocols based on the above-referenced guidance document recommendations and standards, as well as in accordance with in-house protocols.

6.6.7 Do performance data demonstrate equivalence?

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

6.7 Nonclinical Performance Testing

Port tests performed in conformance with *Guidance on 510(k) Submission for Implanted Infusion Ports*, dated October 1990 included assessments of:

- Dimensions
- Septum puncture life
- Intermittent port leak
- Continuous port leak
- Septum blowout
- Fluid dynamics clearance

The following guidance recommended tests were not performed for the following reasons:

- All catheter to port connection tests. All catheters and catheter/port connection systems are part of previously qualified legally marketed devices covered by the predicate device and have been incorporated into the X-Port *isp* port with no change. The only modifications are to the main port body.
- No biocompatibility testing was required. All materials used in the manufacture of the subject device have been previously cleared for similar devices.

In addition, the following verification tests were performed to further demonstrate the safety and efficacy of the subject device for its intended use:

- Flow rate
- Obturation
- Priming volume
- Septum needle insertion force
- Septum needle retention force
- Stem strength
- Suture plug retention
- Top/base assembly strength

6.8 Conclusion

The X-Port *isp* port met all predetermined acceptance criteria.

Based on FDA's decision tree, the X-Port *isp* port is substantially equivalent to the predicate device Hickman Port, K873213, cleared October 27, 1987.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2002

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

Re: K022983
Trade/Device Name: The BardPort® and SlimPort™ Implanted Ports
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: September 6, 2002
Received: September 9, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
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® and SlimPort™ 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: 9-6-02

*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 K022983

Division Sign-Off _____
Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use _____

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

510(k) Number K022983