

DEC - 3 1999

SPECIAL 510(k): DEVICE MODIFICATION
Catheter Innovations, Inc.
Single and Dual-Lumen Implantable Ports - Plastic

K993860

SUMMARY

Prepared November 8, 1999

1. Submitted By:

Catheter Innovations, Inc.
3598 West 1820 South
Salt Lake City, UT 84104-4959
Tel: (801) 954-8444
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2. Contact Person:

Roger L. Richins
V. P. Technology and Regulatory Affairs

3. Device Establishment Registration No.: 1723743

Owner/Operator No.: 9025151

4. Device Identification:

Trade Name: Implantable Port - Plastic
Common Name: Intravascular Implanted Port
Classification Name: Port & Catheter, Implanted, Subcutaneous, Intravascular
Classification: Unclassified
FDA Classification Advisory Committee: 80 - General Hospital
Product Code: LJT – The specific guidelines for Premarket Notification in the LJT product classification are detailed in the "Guidance on 510(k) Submissions for Implanted Infusion Ports" by the CDRH, ODE, Division of Gastroenterology/Urology and General Use Devices (October 1990)

5. Predicate Device(s): K 991897 – Catheter Innovations, Inc. Single and Dual-Lumen Implantable Ports (Approved to Market - October 21, 1999)

K880571 – Originally submitted as Catheter Technologies Port Implantable Vascular Access System (Approved to Market - March 4, 1988) – Currently marketed by Bard Access Systems as "BardPort™ Implanted Ports *with Groshong® catheters*"

K873213 – Hickman® Subcutaneous Port currently marketed by Bard Access Systems

6. Description of Device Modification:

Traditionally, implantable port bodies have been constructed using the same basic biocompatible materials. Port bodies are commonly manufactured from either titanium metal or polysulfone plastic. ***THIS SPECIAL 510(K) DEVICE MODIFICATION IS SUBMITTED TO GAIN APPROVAL FOR THE ADDITION OF A POLYSULFONE BODIED PORT TO OUR EXISTING PORT PRODUCT LINE. There is no difference whatsoever between this product and the predicate K991897 product, other than the use of polysulfone plastic material in the port body!*** There are no changes in design, intended use, and instructions for use or performance when compared to the approved device.

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SUMMARY (Continued)

7. Device Description:

Catheter Innovations, Inc. Implantable Ports are constructed using a combination of traditional implanted port/catheter technology and materials which are well known and proven in the art (over fifteen years of successful use), Bard Access Systems BardPort™ Implanted Ports with Groshong® catheters-*hereafter referred to as BardPorts™* (over eleven years in use) and our own previously approved 510(k) technology. The Catheter Innovations ports, like the BardPorts™ and other traditional ports are implanted within the body. They are used for access to the circulatory system for repeatable or periodic infusion of fluids and/or aspiration of blood. Like many currently marketed ports the Catheter Innovations ports have smooth, contoured titanium (or proposed polysulfone plastic) port bodies with either one (single-lumen) or two (dual-lumen) independent reservoirs.

A radiopaque silicone catheter with one or two lumens is provided with each port body. The catheter may come attached to the port body by the manufacturer or unattached depending on user preference. If the catheter comes attached to the port, at the time of use the health practitioner measures and cuts off the distal end of the catheter to the desired length. If the catheter is not attached to the port when it is purchased, the catheter is placed, then cut off at the proximal end to the desired length and attached to the port by the practitioner. The port is then placed in a small pocket made just under the skin. The port bodies are designed to facilitate secure seating and anchoring in the port pocket.

The ports are accessed by inserting a non-coring needle through the skin and into the self-sealing silicone septum which caps the port body reservoirs.

Both BardPorts™ and Catheter Innovations ports contain a thin silicone membrane within their construction. In both cases these membranes have a small slit or cut through them that acts as a valve. In the BardPorts™ this valve is located at the distal end of the attached catheter. In the Catheter Innovations ports the valve is located in a small plastic polysulfone housing which comes attached to the port body. The catheter is connected to this port through this housing. In both examples the valve is used to control the flow of fluids both into and out of the blood stream. The valve remains closed when the ports are not in use and when subjected to normal central venous pressures. When positive fluid pressure is applied through the reservoir, the valve opens, allowing infusion through the catheter. When negative pressure (aspiration) is applied, the valve opens, allowing for withdrawal of blood into a syringe.

8. Statement of Indications for Use:

The Catheter Innovations ports are designed for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, antibiotics, chemotherapy, analgesics, nutritional therapy, and blood products. They are also indicated for blood specimen withdrawal.

The Catheter Innovations ports, the BardPorts™ (both with and without valve), and the numerous other approved intravascular port and catheter combinations have the same indications for use: long-term access to the central venous system for administration of fluids and for blood specimen withdrawal.

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SUMMARY (Continued)

9. Summary of Technological Characteristics of Device in Relation to Predicate Device(s):

Catheter Innovations currently markets ports which use titanium metal for their port bodies. This proposed device modification would add to our product line a group of ports that use polysulfone plastic as their body material. Both materials have been used for many years in this application by numerous medical device manufacturers, and are commonly used to help improve patient care.

Physical characteristics of Catheter Innovations ports using both titanium and polysulfone port bodies, compared to BardPorts™ with Groshong® and Hickman® catheters, demonstrate that the physical characteristics of the Catheter Innovations ports are identical to the predicate devices for all items listed in the "FDA Guidance on 510(k) Submissions for Implanted Infusion Ports". (October 1990)

Physically, the Catheter Innovations ports differ from the BardPorts™ with Groshong® catheters, only in that the valve in the Catheter Innovations port is located in the catheter-to-port adapter housing, instead of close to the distal tip of the catheter as in the Groshong® catheter.

Additionally, in the BardPorts™ with Groshong® catheters the catheters are supplied in shorter lengths. This length difference is only apparent when the product is removed from the package. In actual use, the catheters are trimmed to length so that their distal tips are located in the distal 1/3 of the Superior Vena Cava (SVC). Thus, the difference in length of catheters, as supplied, is insignificant in relation to end-use of the product.

Both BardPorts™ with Hickman® catheters and Catheter Innovations ports are open-ended, and the distal end is trimmed by the health professional in order to obtain the desired length. Because the Groshong® catheter is close-ended and removal of a distal segment would remove the valve, these catheters are trimmed at the proximal end and subsequently fitted over their port-connecting adapter. Placement and trimming of Catheter Innovations catheters, because they are open-ended, is identical to that of BardPort™ with Hickman® catheters.

Catheter Innovations three-way valve is located in the port-to-catheter adapter housing at the proximal end of the catheter, immediately adjacent to the port body, while the Groshong® three-way valve is located in the distal tip of the catheter in the distal third of the SVC, and directly in the fluid stream path. There are no new safety or effectiveness issues posed by the difference in location of these valves within the body.

Conclusion:

Based on these physical characteristic comparisons, we consider the Catheter Innovations Implantable Ports, using a polysulfone plastic body, to be substantially equivalent to the Catheter Innovations Implantable Ports using a titanium metal body. We also consider this product substantially equivalent to BardPort™ with Groshong® and Hickman® catheters as well as other currently marketed ports in their physical characteristics.

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SUMMARY (Continued)

10. Assessment of Performance Data:

Performance test results indicate Catheter Innovations ports, using polysulfone bodies, are substantially equivalent to predicate device port/catheter combinations for all performance characteristics itemized in the "FDA Guidance on 510(k) Submissions for Implanted Infusion Ports". (October 1990)

Catheter Innovations performance characteristics related to port and valve function were compared to the predicate Catheter Innovation's ports and BardPort™ with Groshong® catheters. Comparison of all other Catheter Innovations port catheter performance characteristics were made to the range of values found for the performance of the predicate BardPort™ with Hickman® and Groshong® catheters. These comparisons indicate that the Catheter Innovations polysulfone port body with catheters performed equivalent to, or better than, the predicate devices for all performance characteristics studied.

Conclusion:

Data indicates that the performance characteristics of the Catheter Innovations ports (using both titanium and polysulfone bodies), are equivalent or superior to the currently marketed BardPort™ Implanted Ports with Groshong® and Hickman® catheters while posing no new safety, efficacy, or performance issues.

11. MRI – Compatible:

The Catheter Innovations Implantable Ports contain no ferrous materials; therefore they are not susceptible to magnetic influence and are "MRI Compatible".

12. Risk Analysis:

A risk analysis was completed on the products covered by this "SPECIAL" 510(k) DEVICE MODIFICATION. This analysis showed that the product constructed with polysulfone plastic used as the port body has the same inherent risks of use as predicate devices and all other central venous access port/catheter products. Their use should be carefully considered before placement. Their placement and care should only be performed by persons knowledgeable of the risks involved and qualified in the procedures required.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 20 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Roger L. Richins
V.P. Technology and Regulatory Affairs
Catheter Innovations, Incorporated
3598 West 1820 South
Salt Lake City, Utah 84104-4959

Re: K993860
Trade Name: Single and Dual-Lumen Implantable Ports-
Plastic
Regulatory Class: Unclassified
Product Code: LJT
Dated: November 8, 1999
Received: November 15, 1999

Dear Mr. Richins:

This letter corrects our substantially equivalent letter of December 3, 1999 regarding the Product Code.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to 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). 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 (Pre-market Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your

premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993860

Device Name: Catheter Innovations Implantable Ports - Plastic

Indications For Use:

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Paloma Cuervo
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993860

Perscription Use
(Per 21 CFR 801.108)

OR

Over -The-Counter