

MAR - 6 1997

K964066

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter Name: Bard Access Systems, Inc. (Division of C.R. Bard, Inc.)
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Date of Preparation: September 30, 1996

B. Device Name: SlimPort™ Dual Low Profile Implanted Port
Trade Name: SlimPort™ Dual Low Profile Implanted Port
Common/Usual Name: Intravascular implanted port
Classification Name: Port & Catheter, Infusion, Intravascular, Subcutaneous, Implanted (80 LJT)

C. Predicate Device Name: Plastic Attachable Dual Port
Trade Name: M.R.I.® Dual Port

D. Device Description:

The SlimPort™ Dual Low Profile Implanted Port has a small, narrow, low, smoothly-shaped profile which minimizes port pocket size, incision size, and tissue displacement. It has an inner titanium dual reservoir assembly with two distinct isolated reservoirs; a one-piece, dual, peanut-shaped solid silicone septum; and a two piece plastic port shell which secures the inner reservoir and septum. The port stem is oriented axially (in line) with the two port reservoirs.

The port will be distributed with two (2) different dual lumen attachable catheters: either a silicone 7 Fr Groshong® (valved, closed tip) dual lumen catheter or a silicone 7 Fr open-ended dual lumen catheter. Port access is performed by percutaneous needle insertion using a non-coring needle. The port may be placed in the chest or arm with the catheter tip located at the junction of the superior vena cava and the right atrium. The device placement site is determined by the clinician, based on medical judgement and patient anatomy.

E. Intended Use:

The SlimPort™ Dual Low Profile Implanted Port is 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.

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F. Technological Characteristics Summary

1. Does the new device have same indication statements?

Yes. The SlimPort™ Dual Low Profile Implanted Port has the same indication for use as the Plastic Dual Port. Both port systems are indicated for patient therapies requiring repeated access to the vascular system. Both port systems can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

2. Does the new device have the same technological characteristics, e.g. Design, materials, etc?

No. The SlimPort™ Dual Low Profile Implanted Port design differs from the plastic port predicate device in that it has an external, plastic outer shell encasing two titanium reservoirs with a titanium stem. The reservoirs are axially oriented (in line) with the port stem. The fluid path from the proximal reservoir (farthest from the stem) is a channel that extends around one side of the circumference of the distal reservoir insert and connects to one side of the dual stem. Dual septa are provided by a one piece, molded, silicone peanut-shaped piece with two raised areas which are secured in place by the plastic port shell. The in-line port design creates a small, narrow, low, smoothly-shaped profile which minimizes port pocket size, incision size and tissue displacement. The principles of operation of the SlimPort™ Dual Low Profile Implanted Port are unchanged from the predicate device.

The 7 Fr dual lumen catheters used with the "Dual SlimPort" are smaller in diameter than the predicate catheter (12 Fr). However, they are within the current range of catheter sizes manufactured by BAS (5 to 13.5 Fr dual lumen). The open-ended catheter differs only in size from the predicate 12 Fr catheter. The tapered D-shaped lumens of the 7 Fr Groshong® catheter are a minor shape modification that optimizes connection of the catheter to the port. The Groshong® catheter remains unchanged from existing Groshong® catheters in regards to manufacturing process, materials and infusion/aspiration performance and specifications.

3. Could the new characteristics affect safety or effectiveness?

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

4. Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are the same for all central venous port/catheter systems.

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

Yes. The FDA's Draft October 1990 "Guidance on 510(k) Submissions for Implanted Infusion Ports" and Draft March 16, 1995 "Guidance on Premarket Notification [510(k)] Submission for Short-term and Long-term Intravascular Catheters." were used to evaluate the device's performance.

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6. Are performance data available to assess effects of new characteristics?

Yes, bench testing was performed on the SlimPort™ Dual Low Profile Implanted Port according to the FDA's Draft October 1990 "Guidance on 510(k) Submissions for Implanted Infusion Ports" and relevant requirements of the Draft March 16, 1995 "Guidance on Premarket Notification [510(k)] Submission for Short-term and Long-term Intravascular Catheters."

7. Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the SlimPort™ Dual Low Profile Implanted Port is substantially equivalent to the currently marketed Plastic (M.R.I.®) Dual Port System.

Based on FDA's decision tree, the SlimPort™ Dual Low Profile Implanted Port is substantially equivalent to the predicate device, the Plastic Dual Attachable Port, K912702, cleared for market September 18, 1991.

G. Performance Data (if applicable)

Testing was performed using the FDA's Draft October 1990 "Guidance on 510(k) submissions for Implanted Infusion Ports" and Draft March 16, 1995 "Guidance on Premarket Notification [510(k)] Submission for Short-term and Long-term Intravascular Catheters." The following guidance testing was performed:

<u>Port Guidance Testing</u>	<u>Catheter Guidance Testing (covered by the referenced port test)</u>
150% Elongation and Leak Test	(Catheter elongation)
Pull to Failure Test	(Tensile strength of catheter)
Non-Cyclic Creep Test	NA
Cyclic Creep Test	(Catheter flexural fatigue tolerance)
Connection Burst Test	(Catheter burst pressure)
Septum Puncture Life Test	NA
Septum Pressure Integrity Test	NA
Clearance Kinetics Test	NA
Gravity Flow Rates Test	(Catheter flow rate)
Priming Volume Test	NA
Test Device Conditioning	NA
Summary	
Physical Characterization	(Dimensions)

The SlimPort™ Dual Low Profile Implanted Port system meets all the acceptance criteria of the testing performed and, based on FDA's decision tree, the SlimPort™ Dual Low Profile Implanted Port is substantially equivalent to the predicate device, the Plastic Attachable Dual Port, K912702, cleared for market on September 18, 1991.

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