

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K961580

PORT-A-CATH® P.A.S. PORT® II Implantable Venous Access Systems

April 23, 1996

I. GENERAL INFORMATION

Applicant's Name and Address: SIMS Deltec, Inc.
1265 Grey Fox Road
St. Paul, MN 55112

Contact Person: Lisa Stone
Manager, Regulatory Affairs
Tel. (612) 628-7224

Common/Usual Name: Subcutaneously Implanted Intravascular Infusion
Port and Catheter

Proprietary Name: PORT-A-CATH® P.A.S. PORT® II Implantable
Venous Access Systems

PORT-A-CATH® P.A.S. PORT® II Fluoro-
Free™ Implantable Venous Access Systems

Equivalence Device Comparison: PORT-A-CATH® P.A.S. PORT® Implantable
Venous Access Systems
(manufactured by SIMS Deltec, Inc.)

PeriPort™ Peripheral Access System
(manufactured by Strato Medical Corp.)

II. DEVICE DESCRIPTION

The P.A.S. PORT® II System is similar to the current commercially available P.A.S. PORT® System. The systems have the identical outlet tube, catheter connector and catheter. The systems are also identical in that the P.A.S. PORT® II System will be made available with a sensor assembly and/or introducer set.

The P.A.S. PORT® II System will be modified to include a new portal shape, an increased septum diameter, an increased septum puncture life, a change in portal housing material (i.e. polysulfone/titanium), the rear suture hole will be filled with silicone, and a vein pick and a winged infusion set will be included with the systems.

III. INTENDED USE OF DEVICE

Because of its low profile, the P.A.S. PORT II system is intended for peripheral placement in the arm. The portal can be implanted in the upper arm above the antecubital space below the axilla, or below the antecubital space in the upper part of the forearm. A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

	PORT-A-CATH® P.A.S. PORT® II Systems	PORT-A-CATH® P.A.S. PORT® Systems	PeriPort™ Peripheral Access System
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	Strato Medical Corp.
INDICATION FOR USE	Because of its low profile, the P.A.S. PORT system is intended for peripheral placement in the arm. The portal can be implanted in the upper arm above the antecubital space below the axilla, or below the antecubital space in the upper part of the forearm. A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.	Because of its low profile, the P.A.S. PORT system is intended for peripheral placement in the arm. A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.	The PeriPort System is indicated for peripheral placement in the midarm, above the antecubital space and well below the subaxillary area, when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.
PORTAL DIMENSIONS (Nominal)			
Height	8.75 mm	10.0 mm	10.2 mm
Length	29.5 mm	26.7 mm	19.5 mm
Width	16.3 mm	16.5 mm	10.2 mm
Septum Diameter	9.5 mm	6.6 mm	5.7 mm
CATHETER DIMENSIONS (Nominal)			
I.D.	1.0 mm	1.0 mm	1.0 mm
O.D.	1.9 mm	1.9 mm	1.7 mm
Length	76 cm	76 cm	76 cm

	PORT-A-CATH® P.A.S. PORT® II Systems	PORT-A-CATH® P.A.S. PORT® Systems	PeriPort™ Peripheral Access System
MATERIALS Portal Housing Septum Connector Catheter	Polysulfone/Titanium Silicone Titanium Polyurethane	Titanium Silicone Titanium Polyurethane	Polysulfone/Titanium Silicone Titanium Polyurethane
CATHETER CONNECTOR	ULTRA-LOCK® Connector	ULTRA-LOCK® Connector	Strain relief connection

V. SUMMARY OF STUDIES

A. **Functional Testing**

In-vitro testing was conducted in accordance with the FDA "Guidance on 510(k) Submissions for Implanted Infusion Ports," dated October 1990. The testing included septum puncture, system leakage and clearance testing.

Biocompatibility testing was conducted on all system components.

B. **Clinical Studies**

Clinical studies were not deemed necessary regarding the PORT-A-CATH® P.A.S. PORT® II Implantable Venous Access System due to its similarity in materials, design and function to current SIMS Deltec systems and other commercially available systems.

C. **Conclusion Drawn from the Studies**

The results of the testing indicated that the PORT-A-CATH® P.A.S. PORT® II Implantable Venous Access System functions according to specification and the materials used in the system are biocompatible. Therefore, the system is considered acceptable for human use.