OCT 19 1999

K992880

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

P.A.S. PORT® Elite Implantable Venous Access System

August 25, 1999

1. 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
Common/Usual Name:	Subcutaneously Implanted Intravascular Infusion Port and Catheter
Proprietary Name:	P.A.S. PORT® Elite Implantable Venous Access System
Equivalence Device Comparison:	P.A.S. PORT® Implantable Venous Access System (manufactured by SIMS Deltec, Inc.) M.R.I.® Low Profile Implanted Port (manufactured by Bard Access Systems)

II. DEVICE DESCRIPTION

The P.A.S. PORT® Elite 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 P.A.S. PORT® Elite System differs from the current commercially available P.A.S. PORT System as follows: modified portal shape, increased septum diameter, new portal housing material, and a pierceable rear suture hole.

The P.A.S. PORT® Elite System will be made available with a sensor assembly and/or introducer set.

III. INTENDED USE OF DEVICE

A P.A.S. PORT® system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

	P.A.S. PORT® Elite Systems	**P.A.S. PORT® Systems**	**M.R.I.® Low Profile Implanted Port**
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	Bard Access Systems
510(K) NUMBER	Subject Device	K875276	—
INDICATION FOR USE	A P.A.S. PORT® system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.	A system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.	The M.R.I. Low Profile Implanted Port is indicated for patient therapy requir-ing repeated access to the vascular system in pedia-tric cases or where a small port profile is desired or required. The port system can be used for infusion of medications, parenteral nutrition solution, blood products or imaging solutions and for the withdrawal of blood samples.
PORTAL DIMENSIONS (Nominal)			
Height	9.5 mm	10.0 mm	10.0 mm
Length	25 mm	26.7 mm	24.8 mm (diameter)
Width	17.2 mm	16.5 mm	—
Septum Diameter	9.7 mm	6.6 mm	10.8 mm
CATHETER DIMENSIONS (Nominal)			
I.D.	1.0 mm	1.0 mm	1.0 mm
O.D.	1.9 mm	1.9 mm	—
Length	76 cm	76 cm	76 cm
MATERIALS			
Portal Housing	Acetal and Titanium	Titanium	Acetal
Septum	Silicone	Silicone	Silicone
Connector	Titanium	Titanium	—
Catheter	Polyurethane	Polyurethane	Silicone
CATHETER CONNECTOR	ULTRA-LOCK® Connector	ULTRA-LOCK® Connector	Strain relief connection

— Information is unknown.

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 system components.

B. Clinical Studies

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

C. Conclusions Drawn from the Studies

The results of the testing indicated that the P.A.S. PORT® Elite 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 1999

Ms. Lisa J. Stone
Manager, Regulatory Affairs
Smiths Industries Medical Systems
SIMS Deltec, Inc.
1265 Grey Fox Road
St. Paul, MN 55112

Re: K992880
Trade Name: P.A.S.PORT® Elite Implantable Venous Access System
Class: Unclassified
Product Code: LJT
Dated: August 25, 1999
Received: August 27, 1999

Dear Ms. Stone:

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 (Premarket 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 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 its toll-free number (800) 638-2041 or (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): K992880

Device Name: P.A.S. PORT® Elite Implantable Venous Access System

Indications for Use:

"A P.A.S. PORT® system is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

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