

JAN 27 2000

K994216

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Plastic Port Implantable Venous Access Systems

December 14, 1999

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

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

Proprietary Name: Plastic Port Implantable Venous Access System

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

M.R.I.® Implanted Ports
(manufactured by Bard Access Systems)

II. DEVICE DESCRIPTION

Plastic Port Implantable Venous Access Systems consist of a plastic portal (standard or Low Profile™ size), silicone or polyurethane catheter, catheter connector, PORT-A-CATH® access needle, blunt needle, and vein pick. The systems will be made available with and without introducer sets.

III. INTENDED USE OF DEVICE

A Plastic Port System is indicated when patient therapy requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

	Plastic Port Systems	PORT-A-CATH® Systems	M.R.I.® Implanted Port
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	Bard Access System
510(K) NUMBER	Subject Device	K830730B K875276 K932840 K942024	Unknown
INDICATION FOR USE	A 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 BardPort 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.
PORTAL AND CONNECTOR MATERIALS			
Housing	Acetal	Polysulfone/Titanium or Titanium	Acetal
Septum	Silicone	Silicone	Silicone
Connector	Polypropylene/Acetal or Silicone	Polypropylene/Titanium or Titanium	Unknown
PORTAL DIMENSIONS – STANDARD SIZE (Nominal)			
Height	14.0 mm	14.7 mm	13.5 mm
Portal Base	30.5 mm	30.5 mm	32.0 mm
Septum Diameter	12.7 mm	11.4 mm	12.7 mm
PORTAL DIMENSIONS – LOW PROFILE SIZE (Nominal)			
Height	10.0 mm	11.5 mm	10.0 mm
Portal Base	25.0 mm	25.0 mm	24.8 mm
Septum Diameter	10.5 mm	9.5 mm	10.8 mm

	Plastic Port Systems	PORT-A-CATH® Systems	M.R.I.® Implanted Port
CATHETER MATERIAL AND DIMENSIONS (Nominal)			
<u>SILICONE</u>			
I.D.	1.0 mm	1.0 mm	1.0 mm
O.D.	2.8 mm	2.8 mm	Unknown
Length	76 cm	76 cm	76 cm
<u>POLYURETHANE</u>			
I.D.	1.0 mm	1.0 mm	n/a ¹
O.D.	1.9 mm	1.9 mm	n/a
Length	76 cm	76 cm	n/a
I.D.	1.6 mm	1.6 mm	n/a
O.D.	2.6 mm	2.6 mm	n/a
Length	76 cm	76 cm	n/a
CATHETER CONNECTOR	SLIDE-LOCK® or CATH-SHIELD® Connector	CATH-SHIELD® or ULTRA-LOCK® Connector	Strain relief connection

III. 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 catheter to port connection, septum puncture, system leakage and clearance testing.

Biocompatibility testing was conducted on system components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding Plastic Port Implantable Venous Access Systems due to their 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 Plastic Port Implantable Venous Access Systems function according to specifications and the materials used in the system are biocompatible. Therefore, these systems are considered acceptable for human use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2000

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

Re: K994216
Trade Name: Deltec Plastic Port Implantable Venous
Access System
Regulatory Class: Unclassified
Product Code: LJT
Dated: December 14, 1999
Received: December 15, 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 (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, 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

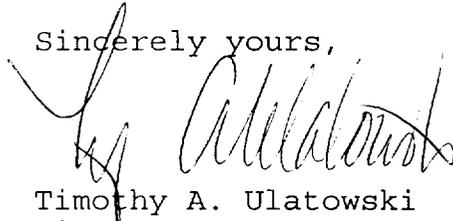
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): _____

Device Name: Plastic Port Implantable Venous Access Systems

Indications for Use:

"A 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 ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

Palma Cucurite

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K994216