19973862

DEC 29 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PORT-A-CATH® Low-Profile™ Implantable Access Systems

October 6, 1997

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® Low-Profile™ Implantable Access Systems
Equivalence Device Comparison:	PORT-A-CATH® P.A.S. PORT® II Implantable Access System (manufactured by SIMS Deltec, Inc.) BardPort™ SlimPort™ Low Profile Port (manufactured by Bard Access Systems)

II. DEVICE DESCRIPTION

The modified PORT-A-CATH® Low-Profile™ Systems are exactly the same in design and function as the current commercially available systems. No change to the product has been made.

III. INTENDED USE OF DEVICE

The indications for use for this device will not change [i.e. A system is indicated when a patient requires repeated vascular access for injection (bolus) or infusion therapy and/or venous blood sampling]. However, the intended use of the device will be modified to include peripheral placement of the device in large or obese patients.

IV. DEVICE COMPARISON

	PORT-A-CATH® Low-Profile™ Systems	**PORT-A-CATH® P.A.S. PORT® II Systems**	**BardPort™ SlimPort™ Low Profile Port**
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	Bard Access Systems
INDICATIONS FOR USE	A system is indicated when a patient requires repeated vascular access for injection (bolus) 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. The portal can be implanted in the upper arm above the antecubital space below the axilla, or below the ante-cubital 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.	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.
INTENDED USE	- Chest placement - Arm placement	- Arm placement	- Chest placement - Arm placement
PORTAL DIMENSIONS (Nominal)			
Height	11.5 mm	8.9 mm	9.8 mm
Length	25.0 mm	23.9 mm	24.7 mm
Width	25.0 mm	16.5 mm	19.0 mm
Septum Diameter	9.5 mm	9.7 mm	9.0 mm

V. SUMMARY OF STUDIES

A. Functional Testing

Functional testing was not deemed necessary, since no changes were made to the product.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the PORT-A-CATH® Low-Profile™ Implantable Access Systems due to their similarity in materials, design and function to current commercially available product (i.e. PORT-A-CATH® P.A.S. PORT® II Implantable Access System and BardPort™ SlimPort™ Low Profile Port).

C. Conclusion Drawn from the Studies

As noted above, no functional testing or clinical studies were deemed necessary regarding the PORT-A-CATH® Low-Profile™ Implantable Access Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1997

Ms. Lisa Stone
Manager Regulatory Affairs
Sims Deltec, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K973862
Trade Name: Port-A-Cath Low Profile Implantable Access Systems
Regulatory Class: Unclassified
Product Code: LTS
Dated: October 6, 1997
Received: October 9, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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): K973862

Device Name: PORT-A-CATH® Low-Profile™ Implantable Access Systems

Indications for Use:

"A system is indicated when a patient requires repeated vascular access for injection (bolus) 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973862

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____