

NOV 18 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PORT-A-CATH® II Trans-Arterial Percutaneous System

K 992697

August 9, 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: Implantable Access System

Proprietary Name: PORT-A-CATH® II Trans-Arterial Percutaneous System

Equivalence Device Comparison: PORT-A-CATH® II Low Profile™ Venous Implantable Access System

PORT-A-CATH® Arterial Implantable Access System

II. DEVICE DESCRIPTION

A PORT-A-CATH® II Trans-Arterial Percutaneous System consists of a portal with a self-sealing silicone septum, accessible by percutaneous needle puncture, and single lumen catheter. The following accessories are provided with the portal and catheter: PORT-A-CATH® access needle, blunt needle, extra-thin wall introducer needle, dilator/sheath assembly, guidewire and syringe.

III. INTENDED USE OF DEVICE

A system is indicated when a patient requires prolonged or repeated intra-arterial infusion.

IV. DEVICE COMPARISON

	PORT-A-CATH® II Trans-Arterial Percutaneous System	PORT-A-CATH® II Low Profile™ System	PORT-A-CATH® Arterial System
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	SIMS Deltec, Inc.
510(K) NUMBER	Subject Device	K942024	K830730B
INDICATIONS FOR USE	A system is indicated when a patient requires prolonged or repeated intra-arterial infusion.	A system is indicated when a patient requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.	A system is indicated when a patient requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.
PORTAL DIMENSIONS (nominal)			
Height	11.5 mm	11.5 mm	13.5 mm
Base	25.0 mm	25.0 mm	25.4 mm
Septum Diameter	9.5 mm	9.5 mm	11.4 mm
CATHETER DIMENSIONS (nominal)			
I.D.	1.9 mm	1.9 mm	2.3 mm
O.D.	1.0 mm	1.0 mm	0.8 mm
Length	100 cm	76 cm	76 cm
MATERIALS			
Portal	Polysulfone/Titanium	Polysulfone/Titanium	Titanium
Septum	Silicone	Silicone	Silicone
Catheter	Polyurethane	Polyurethane	Silicone
CATHETER CONNECTOR	ULTRA-LOCK® Connector	ULTRA-LOCK® Connector	CATH-SHIELD® Connector

V. SUMMARY OF STUDIES

A. Functional Testing

Functional testing was not performed because the PORT-A-CATH® II Trans-Arterial Percutaneous System is functionally the same as the PORT-A-CATH® II Low Profile™ Venous System.

Biocompatibility testing was conducted on the device.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the PORT-A-CATH® II Trans-Arterial Percutaneous System due to its similarity in materials, design and function to the current PORT-A-CATH® II Low Profile™ Venous System.

C. Conclusion Drawn from the Studies

As noted above, no functional testing or clinical studies were deemed necessary regarding the PORT-A-CATH® II Trans-Arterial Percutaneous System. Biocompatibility testing showed that the device materials were biocompatible. Therefore, the device is considered acceptable for human use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

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

Re: K992697
Trade Name: PORT-A-CATH® II Trans-Arterial Percutaneous
System
Regulatory Class: Unclassified
Product Code: LJT
Dated: October 18, 1999
Received: October 19, 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.

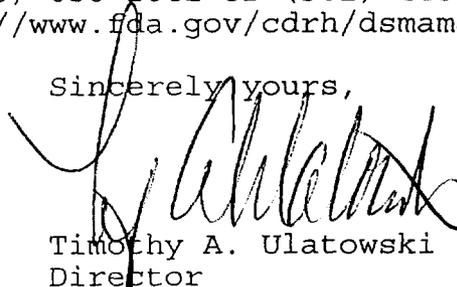
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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): K992697 wmb
~~K992647~~

Device Name: PORT-A-CATH® II Trans-Arterial Percutaneous System

Indications for Use:

"A system is indicated when a patient requires prolonged or repeated intra-arterial infusion."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

Patricia Acosta
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992697