JAN 2 3 2004

K033686

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PORT-A-CATH® II Regional Arterial System

November 21, 2003

I. GENERAL INFORMATION

Applicant's Name and Address:	Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Patricia LaForte Regulatory Affairs Associate
Common/Usual Name:	Implantable Access System
Proprietary Name:	Regional Arterial Port/Catheter System for Local/Regional Drug Delivery
Equivalence Device Comparison:	PORT-A-CATH® II Trans-Arterial Percutaneous System PORT-A-CATH® II Implantable Venous Access System

II. DEVICE DESCRIPTION

A system consists of a portal with a self-sealing silicone septum, accessible by percutaneous needle puncture, a single lumen silicone catheter, a hemostasis sleeve assembly, and a micro-catheter assembly.

III. INTENDED USE OF DEVICE

The PORT-A-CATH® II Regional Arterial Portal System is indicated when patient therapy requires prolonged or repeated intra-arterial access for injection or infusion regimes.

IV. DEVICE COMPARISON

	PORT-A-CATH® II Regional Arterial Drug Delivery System	PORT-A-CATH® II Trans-Arterial Percutaneous System	PORT-A-CATH® II Implantable Venous Access System
MANUFACTURER	Deltec, Inc.	Deltec, Inc.	Deltec, Inc.
510(K) NUMBER	Subject Device	K992697	K932840
INDICATION FOR USE	A system is indicated when patient therapy requires prolonged or repeated intra-arterial infusions.	A system is indicated when patient therapy requires prolonged or repeated intra-arterial infusions.	A system is indicated when patient therapy requires repeated access to the venous system for the parenteral delivery of medications, fluids, and nutritional solutions, and for the sampling of venous blood.
PORTAL AND CONNECTOR MATERIALS			
Housing	Polysulfone/Titanium	Polysulfone/Titanium	Polysulfone/Titanium
Septum	Silicone	Silicone	Silicone
Connector	Polypropylene/Titanium	Polypropylene/Titanium	Polypropylene/Titanium
PORTAL DIMENSIONS (Nominal)			
Height Portal Base Septum Diameter	15.2 mm 30.5 mm 11.4 mm	11.5 mm 25.0 mm 9.5 mm	15.2 mm 30.5 mm 11.4 mm
PORTAL CONNECTING CATHETER			
OD/ID	2.8mm/1.0mm	1.9mm/1.0mm	2.8mm/1.0mm

DELTEC, INC.

Comparison Chart (Continued)

	PORT-A-CATH® II Regional Arterial Drug Delivery System	**PORT-A-CATH® II Trans-Arterial Percutaneous System**	**PORT-A-CATH® II Implantable Venous Access System**
LENGTH MATERIAL	38cm Silicone	76cm Polyurethane	76cm Silicone
PORTAL TUBE CONNECTOR	CATH-SHIELD® Connector	ULTRA-LOCK® Connector	CATH-SHIELD® Connector
INTRA-VASCULAR CATHETER OD/ID Length Material	1.0mm/0.72mm 100cm Pebax/PTFE/Stainless Steel	All same as above (same catheter connects to portal and to vascular system)	All same as above (same catheter connects to portal and to vascular system)
CATHETER TO CATHETER CONNECTOR	Boot- Silicone Clamp – Acetal Sleeve – Tecoflex 93A Bushing – Polyvinyl Chloride (TOTM plasticized)	n/a[1]	n/a
ACCESSORIES Needles Sharps Safety Portal Access Other	 1 blunt / 1 huber 1 Point Lok® 1 GRIPPER PLUS® n/a	 1 blunt / 1 huber n/a n/a Guidewire, introducer needle, introducer, syringe	 1 blunt / 1 huber n/a n/a Vein Pick

[1] n/a = not applicable

III. SUMMARY OF STUDIES

A. Functional Testing

In-vitro testing was conducted in accordance with the FDA "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters," dated March 16, 1995. The testing included tensile strength, flow-rate, catheter stiffness, catheter flexural fatigue, system leakage, and guidewire removal testing.

In-vitro Simulated Life Testing to document performance of the PORT-A-CATH® II Regional Arterial System under simulated, but accelerated, in-use conditions was performed.

In-vivo testing of the PORT-A-CATH® II Regional Arterial System to evaluate the feasibility of the implantation and immediate post-implant performance of an arterial port-catheter system into the hepatic or other target arteries using minimally invasive, image-guided techniques was conducted.

Biocompatibility testing was conducted on system components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding PORT-A-CATH® II Regional Arterial System due to their similarity in materials, design and function to current Deltec systems.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the PORT-A-CATH® II Regional Arterial Portal System functions according to specifications and the materials used in the system are biocompatible. Therefore, these systems are considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2004

Ms. Patricia LaForte
Regulatory Affairs Associate
Smiths Medical MD, Incorporated
1265 Grey Fox Road
Saint Paul, Minnesota 55112

Re: K033686
Trade/Device Name: PORT-A-CATH® II Regional Arterial Portal System
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 21, 2003
Received: November 24, 2003

Dear Ms. LaForte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033686

510(k) Number (if known): K033686

Device Name: PORT-A-CATH® II Regional Arterial Portal System

Indications for Use:

"The PORT-A-CATH® II Regional Arterial Portal System will be indicated when patient therapy requires prolonged or repeated intra-arterial access for injection or infusion regimes."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vicki Hibbard, Interim Branch Chief

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033686

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