K974471

JAN 22 1998

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

## PORT-A-CATH® II Dual-Lumen Low Profile™ Systems

**November 25, 1997**

## I. GENERAL INFORMATION

| | |
|---|---|
| Applicant's Name and Address: | SIMS Deltec, Inc.<br>1265 Grey Fox Road<br>St. Paul, MN 55112 |
| Contact Person: | Lisa Stone<br>Manager, Regulatory Affairs<br>Tel. (612) 628-7224 |
| Common/Usual Name: | Subcutaneously Implanted Intravascular Infusion Port and Catheter |
| Proprietary Name: | PORT-A-CATH® II Dual-Lumen Low Profile™ Implantable Access Systems |
| Equivalence Device Comparison: | PORT-A-CATH® II Dual-Lumen Implantable Access Systems<br>*(manufactured by SIMS Deltec, Inc.)*<br><br>LifePort® Low Profile Dual Lumen System<br>*(manufactured by Strato/Infusaid)* |

## II. DEVICE DESCRIPTION

PORT-A-CATH® II Dual-Lumen Low Profile™ Systems are similar in design and function to the current commercially available PORT-A-CATH® II Dual-Lumen Systems.

These systems differ from current commercially available PORT-A-CATH® systems in that the portal is dimensionally smaller and a dual-lumen polyurethane catheter is being offered.

These systems consist of one low profile dual-lumen portal (titanium/polysulfone), one radiopaque catheter (polyurethane), one catheter connector, one access needle, one blunt needle and one vein pick. Introducer sets and a Fluoro-Free™ system will also be made available.

## III. INTENDED USE OF DEVICE

The PORT-A-CATH® II Dual-Lumen Low Profile™ Systems are indicated when a patient requires repeated venous access for injection (bolus) or infusion therapy and/or venous blood sampling.

## IV. DEVICE COMPARISON

| | PORT-A-CATH® II Dual-Lumen Low Profile™ Systems | PORT-A-CATH® II Dual-Lumen Systems | LifePort® Low Profile Dual Lumen System |
|---|---|---|---|
| MANUFACTURER | SIMS Deltec, Inc. | SIMS Deltec, Inc. | Strato/Infusaid Inc. |
| INDICATION FOR USE | A system is indicated when a patient requires repeated venous access for injection (bolus) or infusion therapy and/or venous blood sampling. | A system is indicated when a patient requires repeated venous access for injection (bolus) or infusion therapy and/or venous blood sampling. | The LifePort system is indicated for patient therapy that requires repeated entry to the vascular system for the delivery of medications, fluids, nutritional solutions and blood products or the withdrawal of venous blood samples. |
| PORTAL DIMENSIONS *(Nominal)* | | | |
| Height | 11.0 mm | 16.0 mm | 10.8 mm |
| Base | 38.7 (L) mm x 23.5 (W) mm | 50.0 (L) mm x 30.0 (W) mm | 40.8 (L) mm x 26.5 (W) mm |
| Septum Diameter | 9.5 mm | 11.4 mm | 10.2 mm |
| MATERIALS | | | |
| Portal Housing | Titanium/Polysulfone | Titanium/Polysulfone | Acetal |
| Septum | Silicone | Silicone | Silicone |
| Catheter | Polyurethane | Silicone | Polyurethane |
| CATHETER DIMENSIONS *(Nominal)* | | | |
| I.D. | 1.0 mm/1.0 mm *or* 1.4 mm/1.4 mm | 1.1 mm/1.1 mm | 1.0 mm/1.0mm |
| O.D. | 2.2 mm *or* 3.2 mm | 3.4 mm | 2.2 mm |
| Length | 76 cm | 76 cm | 76 cm |

## V. SUMMARY OF STUDIES

### A. Functional Testing

*In-vitro* mechanical testing was conducted according to the "Guidance on 510(k) Submissions for Implanted Infusion Ports," October 1990.

Biocompatibility testing was conducted on all system components.

### B. Clinical Studies

Clinical studies were not deemed necessary regarding PORT-A-CATH® II Dual-Lumen Low Profile™ Systems due to their similarity in materials, design and function to current SIMS Deltec commercially available systems.

### C. Conclusions Drawn from the Studies

The results of the testing indicated that PORT-A-CATH® II Dual-Lumen Low Profile™ Systems function according to specification 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

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

JAN 22 1998

Re: K974471
Trade Name: PORT-A-CATH® II Dual-Lumen Low Profile™ Implantable Access Systems
Regulatory Class: Unclassified
Product Code: LJT
Dated: November 25, 1997
Received: November 26, 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. However, you are responsible to determine that the medical devices you use as components in the PORT-A-CATH® II Dual-Lumen Low Profile™ Implantable Access Systems have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your PORT-A-CATH® II Dual-Lumen Low Profile™ Implantable Access Systems. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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 "dsmo@fdadr.cdrh.fda.gov".

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): K974471

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

Indications for Use:

"A system is indicated when a patient requires repeated venous 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 K974471

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