K974013

DEC 17 1997

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**Extension Sets with Microbore Tubing**

**October 20, 1997**

## I. GENERAL INFORMATION

| | |
|---|---|
| Applicant's Name and Address: | SIMS Deltec, Inc.<br>1265 Grey Fox Road<br>St. Paul, MN 55112 |
| Contact Person: | Edward W. Numainville<br>Vice President, Regulatory Affairs and Quality Systems<br>Tel. (612) 628-7166 |
| Common/Usual Name: | Extension Set |
| Proprietary Name: | Extension Set with Microbore Tubing |
| Equivalence Device Comparison: | Extension Set with Anti-Siphon Valve<br>*(manufactured by SIMS Deltec, Inc.)*<br><br>Micro-Volume Extension Set with 0.22 μ Filter<br>*(manufactured by Baxter Healthcare Corp.)* |

## II. DEVICE DESCRIPTION

The purpose of this submission is to offer an alternative, as a matter of customer preference, to the current commercially available SIMS Deltec Extension Sets. The Extension Sets have been modified to include microbore tubing for use in micro-infusions and a new compatible female luer on two of the sets. A 0.2 micron filter has been included on two of the sets and is an air eliminating filter similar to the filter on the Baxter Extension Set. An anti-siphon valve is included on one of the sets and is designed to protect against unregulated gravity infusion that can result from an improperly attached reservoir.

## III. INTENDED USE OF DEVICE

The Extension Set with microbore tubing attaches to the Micro Medication Reservoir for use with the CADD-Micro® pump.

The Extension Set with Anti-Siphon Valve must be used with the MEDICATION CASSETTE™ reservoir to protect against unregulated gravity infusion that can result from an improperly attached reservoir.

## IV. DEVICE COMPARISON

| | **Extension Set with microbore tubing** | **Extension Set with microbore tubing and 0.2 μ filter** | **Extension Set with microbore tubing, 0.2 μ filter, and anti-siphon valve** | **Extension Set with anti-siphon valve K942046** | **Micro-Volume Extension Set with 0.22 μ Filter K811463** |
|---|---|---|---|---|---|
| **MANUFACTURER** | SIMS Deltec, Inc. | SIMS Deltec, Inc. | SIMS Deltec, Inc. | SIMS Deltec, Inc. | Baxter Healthcare Corporation |
| **INTENDED USE** | The Extension Set with microbore tubing attaches to the Micro Medication Reservoir for use with the CADD-Micro® pump. | The Extension Set with microbore tubing attaches to the Micro Medication Reservoir for use with the CADD-Micro® pump. | The Extension Set with Anti-Siphon Valve must be used with the MEDICA-TION CASSETTE™ reservoir to protect against unregulated gravity infusion that can result from an improperly attached reservoir. | The Extension Set with Anti-Siphon Valve is an accessory for fluid delivery devices. It is design-ed to protect against unregulated gravity infusion from improperly attached administration sets used with mechanical infusion pumps in vulnerable patients. | --- |
| **DIMENSIONS (Nominal)** | | | | | |
| **LENGTH** | 45 inches | 60 inches | 60 inches | 4 inches or 60 inches | 60 inches |
| **TUBING I.D.** | 0.020 inches | 0.020 inches | 0.020 inches | 0.040 inches | --- |
| **TUBING O.D.** | 0.088 inches | 0.088 inches | 0.088 inches | 0.105 inches | --- |
| **FILTER** | NO | YES | YES | NO | YES |
| **ANTI-SIPHON VALVE** | NO | NO | YES | YES | NO |

## V. SUMMARY OF STUDIES

### A. Functional Testing

Functional testing performed on the sets to establish their operating parameters.

Biocompatibility testing was conducted on the set components.

### B. Clinical Studies

Clinical studies were not deemed necessary regarding the Extension Sets with Microbore Tubing due to their similarity in materials, design and function to current SIMS Deltec commercially available extension sets.

### C. Conclusions Drawn from the Studies

The results of the testing indicated that the Extension Sets with Microbore Tubing function according to specification and the materials used in the sets are biocompatible. Therefore, these sets are considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

Mr. Edward W. Numainville
Vice-President, Regulatory Affairs and Quality Systems
Sims Deltec, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K974013
Trade Name: Extension Set with Microbore Tubing,
Extension Set with Microbore Tubing and 0.2 μ Filter
Regulatory Class: II
Product Code: FPA
Dated: October 20, 1997
Received: October 22, 1997

Dear Mr. Numainville:

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

K974013

510(k) Number (if known): _____

Device Name: Extension Set with Microbore Tubing, 0.2 μ Filter, and Anti-Siphon Valve

Indications for Use:

" The Extension Set with Anti-Siphon Valve attaches to the MEDICATION CASSETTE™ reservoir for the administration of fluids or medications with CADD® pumps."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Liliana Cucuta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974013

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

K974013

510(k) Number (if known): _____

Device Name: Extension Set with Microbore Tubing, or
Extension Set with Microbore Tubing and 0.2 μ Filter

Indications for Use:

"The Extension Set with microbore tubing attaches to the Micro Medication Reservoir for the administration of fluids or medications with the CADD-Micro® pump."

(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 K974013

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