K974661

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

0.2 μ Bacterial Filter

FEB 1 1 1998

December 12, 1997

I. GENERAL INFORMATION

Applicant's Name and Address:	SIMS Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa J. Stone Manager, Regulatory Affairs Tel. (612) 628-7224
Common/Usual Name:	0.2 μ Bacterial Filter
Proprietary Name:	0.2 μ Bacterial Filter
Equivalence Device Comparison:	Extension Set with microbore tubing and 0.2 μ filter *(manufactured by SIMS Deltec, Inc.)* Disposable I.V. Filter (0.2 μ) *(manufactured by The Medi-Dose® Group)*

II. DEVICE DESCRIPTION

The purpose of this submission is to offer an 0.2 μ Bacterial Filter with standard luer connections for use with administration sets or extension sets used with fluid delivery devices. The subject device is intended to be "added-on" to an administration set or extension set.

The filter is an air-eliminating filter and is circular in shape with a center vent. The inlet of the filter is a standard female luer and the outlet of the filter is a standard male luer. The filter membranes are enclosed within a plastic case which is approximately 1.22 in. (width) x 1.85 in. (length).

III. INTENDED USE OF DEVICE

The 0.2 μ Bacterial Filter can be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications.

IV. DEVICE COMPARISON

	0.2 μ Bacterial Filter	Extension Set with microbore tubing and 0.2 μ filter	Disposable I.V. Filter (0.2 μ)
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	The Medi-Dose® Group
INDICATION FOR USE	The 0.2 μ Bacterial Filter can be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications.	The Extension Set with microbore tubing attaches to the Micro Medication Reservoir for the administration of fluids or medications with the CADD-Micro® pump.	—
FILTER SIZE	0.2 μ	0.2 μ	0.2 μ
FILTRATION SURFACE AREA	4.3 cm^2	0.3 in^2	—
ADD-ON FILTER WITH LUER LOCK CONNECTION(S)	YES	NO	YES

V. SUMMARY OF STUDIES

A. Functional Testing

Functional testing was performed on the filter to establish its operating parameters.

Biocompatibility testing was conducted on the filter.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the filter due to its similarity in materials, design and function to current commercially available filters and extension sets with in-line filters.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the filter functions according to specification and the filter meets the biocompatibility requirements. Therefore, the filter is 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 J. Stone
Manager, Regulatory Affairs
Sims Deltec, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

FEB 11 1998

Re: K974661
Trade Name: 0.2 μ Bacterial Filter
Regulatory Class: II
Product Code: FPB
Dated: December 12, 1997
Received: December 15, 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

K974661

510(k) Number (if known): _____

Device Name: 0.2 μ Bacterial Filter

Indications for Use:

"The 0.2 μ Bacterial Filter can be used with administration sets or extension sets for removal of particulate matter during the administration of fluids or medications."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974661

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