

K980583

APR 27 1998

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Alternate 0.2µ Filter for use with  
Deltec Extension Set with Anti-Siphon Valve  
and CADD® Administration Set with 0.2µ Filter and Anti-Siphon Valve  
February 12, 1998**

**I. GENERAL INFORMATION**

Applicant's Name  
and Address:

SIMS Deltec, Inc.  
1265 Grey Fox Road  
St. Paul, MN 55112

Contact Person:

David H. Short  
Director, Regulatory and Clinical Affairs  
Tel. (612) 628-7214

Common/Usual Name:

Extension Set Administration Set

Proprietary Name:

Extension Set with 0.2µ Filter and Anti-Siphon Valve  
CADD® Administration Set with 0.2µ Filter and Anti-Siphon Valve

Equivalence Device  
Comparison:

Extension Set with Anti-Siphon Valve  
*(manufactured by SIMS Deltec, Inc.)*

CADD® Administration Set with 0.2µ Filter  
and Anti-Siphon Valve  
*(manufactured by SIMS Deltec, Inc.)*

Filter Set with 0.22µ Filter, y-Injection Site and  
OPTION-LOK®  
*(manufactured by ABBOTT LABORATORIES.)*

**II. DEVICE DESCRIPTION**

The purpose of this submission is to offer an alternate 0.2µ filter, as a matter of customer preference, for use with the SIMS Deltec Extension Set with Anti-Siphon Valve and CADD® Administration Set with 0.2µ Filter and Anti-Siphon Valve. The 0.2µ filter is similar to the filter on the Abbott Laboratories' Filter Set with 0.22µ Filter. An integral anti-siphon valve is included and is designed to protect against unregulated gravity infusion that may result from an improperly attached reservoir.

## **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Alternate 0.2 $\mu$  Filter for use with  
Deltec Extension Set with Anti-Siphon Valve  
and CADD<sup>®</sup> Administration Set with 0.2 $\mu$  Filter and Anti-Siphon Valve  
February 12, 1998**

### **III. INTENDED USE OF DEVICE**

The Extension Set with 0.2 $\mu$  filter and anti-siphon valve attaches to the MEDICATION CASSETTE<sup>™</sup> reservoir for the administration of fluids or medications with CADD-1<sup>®</sup>, CADD-PCA<sup>®</sup>, CADD-PLUS<sup>®</sup>, CADD-Prizm<sup>®</sup> pumps.

The CADD<sup>®</sup> Administration Set with 0.2 $\mu$  filter and anti-siphon valve is intended for use with CADD-1<sup>®</sup>, CADD-PCA<sup>®</sup>, CADD-PLUS<sup>®</sup>, CADD-Prizm<sup>®</sup> pumps for the administration of fluids or medications.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 27 1998

Mr. David H. Short  
Director, Regulatory and Clinical Affairs  
SIMS Deltec, Incorporated  
1265 Grey Fox Road  
St. Paul, Minnesota 55112

Re: K980583  
Trade Name: Extension Set with 0.2 $\mu$  Filter and Anti-Siphon Valve CADD®  
Regulatory Class: II  
Product Code: EPA  
Dated: February 13, 1998  
Received: February 17, 1998

Dear Mr. Short:

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 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

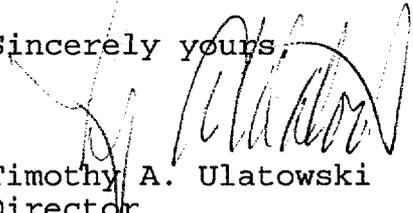
Page 2 - Mr. Short

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

K980583

510(k) Number (if known): \_\_\_\_\_

Device Name: CADD® Administration Set with 0.2µ Filter and Anti-Siphon Valve

Indications for Use:

"The CADD® Administration Set with 0.2µ filter and anti-siphon valve is intended for use with CADD-1®, CADD-PCA®, CADD-PLUS®, CADD-Prizm® pumps for 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)

*Patricia Cicente*

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

510(k) Number K980583

Prescription Use

OR

Over-The Counter Use

(Per 21 CFR 801.109)