K991301

JUN 9 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CADD-Prizm® High Volume Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve

CADD® Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve

April 15, 1999

I. GENERAL INFORMATION

Applicant's Name and Address:	SIMS Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Edward W. Numainville Vice President, Regulatory Affairs and Quality Systems
Common/Usual Name:	Administration Set
Proprietary Name:	CADD-Prizm® High Volume Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve CADD® Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve Hereafter, collectively referred to as "Administration Sets".
Equivalence Device Comparison:	CADD-Prizm® High Volume Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve CADD® Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve

II. DEVICE DESCRIPTION

The purpose of this submission is to offer an alternate 1.2 μ Filter for manufacturing standardization and use with the current SIMS Deltec Administration Sets. The Administration Sets are made up of the following components: bag spike, tubing, housing, 1.2 μ filter, tubing clamp, injection site (found on the CADD-Prizm® High Volume Administration Set only), male luer connector with protective cap, and anti-siphon valve.

III. INTENDED USE OF THE DEVICE

The CADD-Prizm® High Volume Administration Set is designed for use with the CADD-Prizm® pump to allow fluid delivery from an IV bag.

The CADD® Administration Set is designed to be used with a variety of CADD® pumps to allow fluid delivery from an IV bag.

IV. DEVICE COMPARISON

	CADD-Prizm® High Volume Administration Set with 1.2 µ Filter and Add-on Anti-siphon Valve	CADD-Prizm® High Volume Administration Set with 1.2 µ Filter and Add-on Anti-siphon Valve	CADD® Administration Set with 1.2 µ Filter and Add-on Anti-siphon Valve	CADD® Administration Set with 1.2 µ Filter and Add-on Anti-siphon Valve
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	SIMS Deltec, Inc.	SIMS Deltec, Inc.
510(K) NUMBER	Subject Device	K943310	Subject Device	K933390 K954870
INDICATIONS FOR USE	The CADD-Prizm® High Volume Administration Set is designed for use with the CADD-Prizm® pump to allow fluid delivery from an IV bag.	The CADD-Prizm® High Volume Administration Set is designed for use with the CADD-Prizm® pump to allow fluid delivery from an IV bag.	The CADD® Administration Set is designed to be used with a variety of CADD® pumps to allow fluid delivery from an IV bag.	The CADD® Administration Set is designed to be used with a variety of CADD® pumps to allow fluid delivery from an IV bag.
DIMENSIONS (Nominal)				
LENGTH	120 in.	120 in.	94 in.	94 in.
I.D.	0.100	0.100	0.060 in. (coiled tubing)	0.060 in. (coiled tubing)
O.D.	0.164	0.164	0.105 in. (coiled tubing)	0.105 in. (coiled tubing)
FILTER	YES	YES	YES	YES
ANTI-SIPHON VALVE	YES	YES	YES	YES

V. SUMMARY OF STUDIES

A. Functional Testing

Functional specification testing was performed on the alternate filter when used with the anti-siphon valve.

Biocompatibility testing was conducted.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the new Administration Sets due to their similarity in materials, design and function to current commercially available SIMS Deltec Administration Sets.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the filter functions according to specification and the set meets the biocompatibility requirements. Therefore, the Administration 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

JUN 9 1999

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

Re: K991301
Trade Name: CADD-Prizm® High Volume Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve
Regulatory Class: II
Product Code: FPA
Dated: April 15, 1999
Received: April 16, 1999

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 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 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

K991301

510(k) Number (if known): _____

Device Name: CADD-Prizm® High Volume Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve

Indications for Use:

"The CADD-Prizm® High Volume Administration Set is designed for use with the CADD-Prizm® pump to allow fluid delivery from an IV bag."

(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 K991301

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

K991301

510(k) Number (if known): _____

Device Name: CADD® Administration Set with 1.2 μ Filter and Add-on Anti-siphon Valve

Indications for Use:

"The CADD® Administration Set is designed to be used with a variety of CADD® pumps to allow fluid delivery from an IV bag."

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

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