

2/12/99

K990083

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CADD® Administration Set and Accessories

January 6, 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
Tel. (651) 628-7166

Common/Usual Name:

Administration Set and Accessories

Proprietary Name:

CADD® Administration Set
CADD® 250 ml Flexible Medication Reservoir
Modified Security Shell
Security Shell Adapter

Equivalence Device
Comparison:

CADD® Administration Set
(*manufactured by SIMS Deltec, Inc.*)

Sabreset™ 560500-100 Administration Set with 100 ml
Bag and Cassette
(*manufactured by Sabratek*)

II. DEVICE DESCRIPTION

The purpose of this submission is to offer an additional CADD® Administration Set that can be used with three new accessories; i.e. a 250 ml Flexible Medication Reservoir, a Modified Security Shell, and a Security Shell Adapter; for the delivery of fluids with SIMS Deltec CADD® ambulatory infusion pumps. The Modified Security Shell and Security Shell Adapter provide a "locked" compartment for the 250 ml Flexible Medication Reservoir to deter unauthorized access to its contents. An add-on anti-siphon valve is included with the set. This valve is designed to protect against unregulated gravity infusion that can result from an improperly attached reservoir.

III. INTENDED USE OF DEVICE

The CADD® Administration Set is designed to be used with Deltec CADD® Pumps to allow fluid delivery from a flexible remote bag with female luer connector.

IV. DEVICE COMPARISON

	SIMS Deltec CADD® Administration Set with Accessories	Sabratek Sabraset™ 560500-100 Administration Set with 100 ml Bag & Cassette	SIMS Deltec CADD® Administration Set
INTENDED USE	The CADD® Administration Set is designed to be used with Deltec CADD® Pumps to allow fluid delivery from a flexible remote bag with female luer connector.	For use with the Sabratek 6060 Homerun® pump.	The CADD® Administration Set is designed to be used with a variety of Deltec CADD® Pumps to allow fluid delivery from a remote bag.
CAN BE USED WITH REMOTE FLEXIBLE RESERVOIR	YES	YES	YES
CAN BE USED WITH AN ENCLOSURE AND REMOTE FLEXIBLE RESERVOIR TO LIMIT ACCESS TO MEDICATION	YES (Modified Security Shell, Security Shell Adapter, and 250 ml Flexible Medication Reservoir) <i>Subject of this submission.</i>	YES	YES
FREE FLOW PROTECTION MECHANISM	YES (Add-on anti-siphon valve)	UNKNOWN	YES (Add-on anti-siphon valve)
DIMENSIONS (NOMINAL)			
LENGTH	69 in.	56 in.	77 in.
TUBING I.D.	0.040 in.	UNKNOWN	0.040 in.
TUBING O.D.	0.105 in.	UNKNOWN	0.105 in.
PRIMING VOLUME	2 ml	3 ml	2.3 ml

V. SUMMARY OF STUDIES

A. Functional Testing

Biocompatibility testing was conducted on the set's fluid path components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the CADD[®] Administration Set and Accessories due to their similarity in materials, design and function to other SIMS Deltec products and the Sabratek Set and Accessories.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the fluid path materials used in the CADD[®] Administration Set and Accessories are biocompatible. Therefore, these products are considered acceptable for human use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

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

Re: K990083
Trade Name: CADD® Administration Set, and Accessories
Regulatory Class: II
Product Code: FPA
Dated: January 6, 1999
Received: January 11, 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.

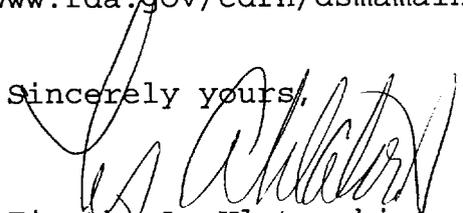
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

Page 2 - Mr. Numainville

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

K990083

510(k) Number (if known): _____

Device Name: CADD® Administration Set with Accessories

Indications for Use:

"The CADD® Administration Set is designed to be used with Deltec CADD® Pumps to allow fluid delivery from a flexible remote bag with female luer connector."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

Roberto Cuervo

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K990083