K991599

JUN 15 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Luer Activated Needleless Injection Site for use with
Various Deltec Administration Sets

May 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
Common/Usual Name:	Administration Set with Injection Site
Proprietary Name:	For example: CADD-Prizm® High Volume Administration Set with 0.2 μ filter, Add-On Anti-Siphon Valve, bag spike, luer activated needleless injection site, male luer, and clamp
Equivalence Device Comparison:	ULTRASITE™ Needle-free IV System

II. DEVICE DESCRIPTION

The purpose of this submission is to offer an alternate injection site ("Luer Activated Needleless Injection Site") for use with various Deltec administration sets. The injection site is a valve and is accessed using needleless syringes or IV administration sets.

III. INTENDED USE OF THE DEVICE

The alternate injection site is designed for use with various SIMS Deltec administration sets or syringes for fluid delivery.

IV. DEVICE COMPARISON

	Alternate Injection Site for use with Various Deltec Administration Sets	Standard Injection Site used on the CADD-Prizm® High Volume Administration Set	ULTRASITE™ Needle-free IV System
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	B. Braun Medical Inc.
510(K) NUMBER	Subject Device	K943310	Unknown
INDICATIONS FOR USE	Designed for use with various SIMS Deltec administration sets or syringes for fluid delivery.	Designed for use with various SIMS Deltec administration sets for fluid delivery.	The ULTRASITE™ Valve is a specially designed valve for use on intravenous lines. It allows you to use a syringe or IV administration set without a needle.
NEEDLE-FREE VALVE	YES	NO	YES
INTEGRAL TO ADMINISTRATION SET	YES	YES	NO

V. SUMMARY OF STUDIES

A. Functional testing

Functional specification testing was performed on the alternate injection site.

Biocompatibility testing was conducted.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the alternate injection site due to its similarity in materials, design and function to current commercially available injection sites.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the alternate injection site functions according to specification and it meets the biocompatibility requirements. Therefore, the alternate injection site is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 1999

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

Re: K991599
Trade Name: CADD® Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 6, 1999
Received: May 10, 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

K 991599

510(k) Number (if known): _____

Device Name: Luer Activated Needleless Injection Site

Indications for Use:

The luer activated needleless injection site is designed for use with various SIMS Deltec, Inc. administration sets or syringes for fluid delivery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991599

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