K982836

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
for the
CADD-Legacy™ Plus MODEL 6500 AMBULATORY INFUSION SYSTEM

NOV 2 1998

I. GENERAL INFORMATION

Common/Usual Name:	Ambulatory Infusion Pump
Proprietary Name:	CADD-Legacy™ Plus Model 6500 Ambulatory Infusion System
Applicant's name and address:	SIMS Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Equivalence device comparison:	CADD-PLUS® Ambulatory Infusion Pump and CADD-Prizm® VIP Model 6100 Ambulatory Infusion System

II. DEVICE DESCRIPTION

The CADD-Legacy™ Plus Model 6500 ambulatory infusion pump is similar in design, function, and intended use to Deltec's CADD-PLUS® Ambulatory Infusion Pump and the CADD-Prizm® VIP Model 6100 Ambulatory Infusion System . The Model 6500 pump provides measured drug therapy for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space or subarachnoid space delivery to patients in hospital or outpatient settings. The pump is capable of storing one delivery application. The delivery application resident in the Model 6500 pump and the subject of this 510(k) Notification consists of the continuous/intermittent delivery application.

III. ALTERNATIVES

Alternatives to the CADD-Legacy™ Plus Model 6500 pump include the use of other commercially available ambulatory infusion pumps, such as Deltec's CADD-PLUS® and CADD-Prizm® VIP Ambulatory Infusion Pumps.

IV. POTENTIAL ADVERSE EFFECTS

The potential direct adverse effects that may occur when using the CADD-Legacy™ Plus Model 6500 pump, as well as other commercially available non-implantable ambulatory infusion pumps, include the possibility of over-infusion, under-infusion, or no infusion.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
for the
CADD-Legacy™ Plus MODEL 6500 AMBULATORY INFUSION SYSTEM

V. SUMMARY OF STUDIES

A. Functional Testing

Test plans associated with software validation, verification of software controlled programming functions, and software related to proper pump operation were certified for the CADD-Legacy™ Plus Model 6500 Ambulatory Infusion System.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the use of the CADD-Legacy™ Plus Model 6500 Ambulatory Infusion System.

VI. CONCLUSIONS DRAWN FROM THESE STUDIES

Based upon the information provided above, the CADD-Legacy™ Plus Model 6500 Ambulatory Infusion System is substantially equivalent to other commercially available ambulatory infusion systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1998

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

Re: K982836
Trade Name: CADD-Legacy™ Plus, Model 6500, Ambulatory Drug Infusion System
Regulatory Class: II
Product Code: FRN
Dated: August 12, 1998
Received: August 12, 1998

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

INDICATIONS FOR USE

510(k) Number (if known): K982836

Device Name: CADD-Legacy™ Plus Model 6500 Ambulatory Infusion Pump

Indications For Use:

"The CADD-Legacy™ pump is suitable for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space, or subarachnoid space infusion."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1/2/96)

Patricia Cusenza
(Division Sign-Off)
Division of Dental Infection Control,
and General Hospital Devices
510(k) Number K982835