K973917
JAN. 9, 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
for the
PC-Communication and Pump Communications System
used with the CADD-Prizm™ Model 6100 Ambulatory Infusion System

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:	PC-Communications System and Pump Communications System
Proprietary Name:	CADD-Diplomat™ PC Communications System and the CADD-Ambassador™ Pump Communications System
Equivalence Device Comparison:	Sabratek's Homerun™ Model 6060 with MediVIEW™ Software Package and Deltec's CADD-Prizm™ Model 6100 Ambulatory Infusion System

II. DEVICE DESCRIPTION

The PC-Communications System ("PC System") and Pump Communications System ("Pump System") are two products that will be used with CADD-Prizm™ Model 6100 Ambulatory Infusion Pumps. The PC System and the Pump System products are substantially equivalent to Sabratek's MediVIEW™ Software Package used with their Homerun™ Model 6060 Ambulatory Infusion Pump and the current Modem used with SIMS Deltec's CADD-Prizm™ Model 6100 Ambulatory Infusion Pump. The products allow communications between a personal computer and an ambulatory infusion pump, either locally or remotely via modem over telephone lines and allow the clinician and patient to converse during PC to pump, or pump-to-pump communications, respectively.

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III. INTENDED USE OF DEVICE

To allow communication between a personal computer and the CADD-Prizm™ Ambulatory Infusion Pump, Model 6100,or pump-to-pump, either remotely or locally via a modem over telephone lines.

IV. DEVICE COMPARISONS

Feature/Function	Deltec PC System with CADD Prizm™ Pump	Sabratek MediVIEW ™ with 6060 Pump	Deltec Current Modem	Deltec New ASVD Modem
IBM compatible PC software program.	Yes	Yes		
Allows direct PC to pump cable connection.	Yes	Yes		
Allows connection to pump via modem and telephone lines.	Yes	Yes		
Program uses modem with simultaneous voice and data feature.	Yes	Yes		
User reviews and controls pump via image of pump on the PC screen.	Yes	Yes		
User can monitor pump via image of pump on the PC screen.	Yes	Yes		
User can retrieve reports from pump.	Yes	Yes		
User can view, print and save reports to disk.	Yes	Yes		
User can retrieve, view, print reports previously saved to disk.	Yes	Yes		
User can capture patient data to formulate outcomes management database.	Yes	No		
Program documents "before and after" snapshot of the pump's program in a communications log.	Yes	No		
Program can retrieve information on what accessories are attached to pump, e.g. AC adapter, air detector, cassette, etc.	Yes	No		
Kit contains separate analog phone			Yes	No
Kit contains analog simultaneous voice data modem that plugs directly into clinician's and patient's own phone			No	Yes
Patient and clinician can voice communicate during communication setting			No	Yes

V. SUMMARY OF STUDIES

A. Functional Testing

Test plans associated with the validation of software controlled interface functions with respect PC - Communications System and Pump Communications System for use with CADD-Prizm™ Ambulatory Infusion Systems, Model 6100.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the use of the PC - Communications System and Pump Communications System with the CADD-Prizm™ Ambulatory Infusion System, Model 6100.

C. Conclusions Drawn from Studies

Based upon the information provided above, the use of the PC - Communications System and Pump Communications System with the CADD-Prizm™ Ambulatory Infusion System, Model 6100 is substantially equivalent to Sabratek's MediVIEW™ Software Package used with their Homerun™ Model 6060 Ambulatory Infusion Pump and the current Modem used with SIMS Deltec's CADD-Prizm™ Model 6100 Ambulatory Infusion Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN - 9 1998

Re: K973917
Trade Name: CADD-Diplomat™ PC Communications System
and the CADD-Ambassador™ Pump Communications System
Regulatory Class: II
Product Code: FRN
Dated: October 14, 1997
Received: October 15, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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): Unknown K973917

Device Name: PC- Communications System and Pump Communications System for use with CADD-Prizm™ Ambulatory Infusion System, Model 6100.

Indications For Use:

" To allow communication between a personal computer and the CADD-Prizm™ Ambulatory Infusion Pump, Model 6100, or pump-to-pump, either remotely or locally via a modem over telephone lines."

(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)