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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
for the  
CADD-Prizm™ MODEL 6100 AMBULATORY INFUSION SYSTEM

**I. GENERAL INFORMATION**

Common/Usual Name: Ambulatory Infusion Pump

Proprietary Name: CADD-Prizm™ Model 6100  
Ambulatory Infusion System

Applicant's name and address: SIMS Deltec, Inc.  
1265 Grey Fox Road  
St. Paul, MN 55112

Equivalence device comparison: Abbott Laboratories AIM™ System and  
Deltec's CADD-Prizm™ Model 6100 PCS  
(Pain Control System).

**II. DEVICE DESCRIPTION**

The CADD-Prizm™ Model 6100 ambulatory infusion pump is similar in design, function, and intended use to Abbott Laboratories AIM™ System and Deltec's CADD-Prizm™ Model 6100 PCS (Pain Control System). The Model 6100 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 to four delivery applications at one time. The delivery applications supplied for use with the Model 6100 pump and the subject of this 510(k) Notification are the TPN delivery application, continuous delivery application and the intermittent delivery application.

**III. ALTERNATIVES**

Alternatives to the CADD-Prizm™ Model 6100 pump include the use of other commercially available ambulatory drug infusion pumps such as Abbott AIM™ System.

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**V. POTENTIAL ADVERSE EFFECTS**

The potential direct adverse effects that may occur when using the CADD-Prizm™ Model 6100 pump, as well as other commercially available non-implantable ambulatory infusion pumps, include the possibility of over-infusion, under-infusion, or no infusion.

**VI. 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-Prizm™ Model 6100 Ambulatory Infusion System.

**B. Clinical Studies**

Clinical studies were not deemed necessary regarding the use of the CADD-Prizm™ Model 6100 Ambulatory Infusion System.

**VII. CONCLUSIONS DRAWN FROM THESE STUDIES**

Based upon the information provided above, the CADD-Prizm™ Model 6100 Ambulatory Infusion Pump is substantially equivalent to other commercially available ambulatory infusion systems.