

K960957

510(k) Summary of Safety and Effectiveness
Date Prepared: March 4, 1996

JUN - 4 1996

I. GENERAL INFORMATION

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

Contact: David H. Short
Manager, Regulatory Affairs
(612)628-7214

II. PRODUCT INFORMATION

Common/Usual Name: Battery Pack

Classification Name: Unknown

Proprietary Name: External Power Source (EPS) System,
Alternate Power Pack (nickel-metal hydride)

III. EQUIVALENCE DEVICE COMPARISON

SIMS Deltec's External Power Source (EPS) System, Power Pack (nickel cadmium, NiCad)

IV. DEVICE DESCRIPTION

The External Power Source (EPS) System is comprised of a rechargeable power pack, AC adaptor, battery adaptor, notched battery door, and replacement battery pack for the power pack. The EPS System was developed as an alternate power source to 9 volt batteries for various CADD[®] pumps Deltec manufactures. The EPS System is designed for use with CADD-1[®] pump, CADD-PLUS[®] pump, CADD-PCA[®] (Models 5800 and 5800R) pumps, and the CADD-Prizm[™] pump. An alternate rechargeable power pack with replaceable nickel-metal hydride (NiNH) batteries has been developed and the subject of this 510(k) Notification.

510(k) Summary of Safety and Effectiveness
Date Prepared: March 4, 1996

IV. DEVICE COMPARISON

Provided in Table 1 is a feature comparison of the EPS System Power Pack with NiMH batteries and the EPS System Power Pack with NiCad batteries.

Table 1. Comparison Chart

	External Power Source (EPS) System Alternate Power Pack	External Power Source (EPS) System Power Pack
Manufacturer	SIMS Deltec, Inc.	SIMS Deltec, Inc.
Power Pack Feature		
Battery Chemistry	nickel-metal hydride	nickel cadmium
Rechargeable Power Pack	YES	YES
Replaceable Battery Pack	YES	YES
Low Battery Alarm	YES	YES
Ready Indicator Lights	YES	NO
Operating Temperature	2°C to 40°C	2°C to 40°C
Weight	≈570 g	≈570 g

V. INTENDED USE

The External Power Source (EPS) System is designed to provide an alternative source of power for the following Deltec Pumps: CADD-1[®], CADD-PCA[®], CADD-PLUS[®], CADD-TPN[®], and CADD-Prizm™ ambulatory infusion pumps.

VI. SUMMARY OF STUDIES

A. Functional Testing

Function testing was conducted using the alternate power pack of the External Power Source (EPS) System in accordance with the Rechargeable Battery Preliminary Guidance for Data to be Submitted to the Food and Drug Administration in Support of Premarket Notification Applications (January 1994). Based upon the testing that was conducted, the power pack with NiMH batteries performed as intended and within specification.

B. Clinical Studies

Clinical studies were not deemed necessary.

510(k) Summary of Safety and Effectiveness
Date Prepared: March 4, 1996

VII. CONCLUSION

Based upon the information provided above, the alternate power pack developed for use in the External Power Source (EPS) System is suitable for its intended use, i.e., as an alternative source of power for the following Deltec Pumps: CADD-1[®], CADD-PCA[®], CADD-PLUS[®], CADD-TPN[®], and CADD-Prizm™ ambulatory infusion pumps.