

K955180

510(k) Summary
Date Prepared: November 8, 1995

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: Ambulatory Infusion Pumps

Classification Name: Infusion Pump

Proprietary Name: CADD-PCA[®] Model 5800 Pump
CADD-PCA[®] Model 5800R Pump
CADD-Micro[®] Model 5900 Pump
CADD-Prizm[™] Model 6100 Pump

III. EQUIVALENCE DEVICE COMPARISON

IPI AlgoLine[™] Catheter Kits manufactured by PS Medical Coporation, Goleta, CA.

IV. DEVICE DESCRIPTION

The subject devices are microcomputer controlled ambulatory infusion pumps intended for the delivery of medication via various parenteral routes, i.e., intravenous, intra-arterial, subcutaneous, intraperitoneal, or epidural space infusion. The purpose of this 510(k) Notification is to add subarachnoid space infusion to the labeling and thereby expanding the intended use of each pump. The subject devices, as a matter of course, will be used for the delivery of medication through catheters that have this indication.

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IV. DEVICE COMPARISON

Provided in Table 1 is a comparison of devices and their respective indications for use.

Table 1. Comparison of indications for use of various devices.

	CADD-Prizm™ Pump	CADD-PCA® Pump (Models 5800 & 5800R)	CADD-Micro® Pump	AngoLine™ Catheter Kits
Manufacturer	SIMS Deltec, Inc.	SIMS Deltec, Inc.	SIMS Deltec, Inc.	IPI PS Medical Corporation
SYSTEM				
Microcomputer controlled pump	YES	YES	YES	n/a
INDICATIONS FOR USE				
Intravenous	YES	YES	YES	n/a
Intra-arterial	YES	NO	YES	n/a
Subcutaneous	YES	YES	YES	n/a
Intraperitoneal	YES	NO	YES	n/a
Epidural space	YES	YES	YES	YES
Subarachnoid space	NO	NO	NO	YES

V. INTENDED USE

CADD-PCA® Model 5800 or 5800R Pump:

The CADD-PCA pump is indicated for intravenous, subcutaneous, epidural space or subarachnoid space infusions.

CADD-Micro® Model 5900 Pump:

The CADD-Micro pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space or subarachnoid space microinfusions.

CADD-Prizm™ Model 6100 Pump:

The CADD-Prizm pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space or subarachnoid space infusions.

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VI. SUMMARY OF STUDIES

A. Functional Testing

No software and/or functional modifications were required as it relates to the addition of the subarachnoid space infusion indication to the labeling of each subject device, therefore, no functional testing was deemed necessary.

B. Clinical Studies

Clinical studies were not deemed necessary.

VII. CONCLUSION

Based upon the information provided above, the addition of subarachnoid space infusion to the labeling of each subject device is substantially equivalent to the labeling of commercially available catheters, such as the IPI AlgoLine™ Catheter Kits manufactured by PS Medical Corporation, with this indication.