

K963009

510(k) Summary of Safety and Effectiveness
Date Prepared: May 20, 1996

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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: Subcutaneous Infusion Set

Classification Name: Infusion Set

Proprietary Name: Deltec Subcutaneous Infusion Set

III. EQUIVALENCE DEVICE COMPARISON

SIMS Deltec's Subcutaneous Infusion Set and Micro Med's 42" Winged Sub-Q Infusion Set.

IV. DEVICE DESCRIPTION

The Deltec Subcutaneous Infusion Set consists of a needle with attached wing, extension tubing and female luer.

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IV. DEVICE COMPARISON

Provided in Table 1 is a feature comparison of commercially available subcutaneous infusion sets.

Table 1. Comparison Chart

	Deltec Subcutaneous Infusion Set	Subcutaneous Infusion Set	Micro Med 42" Winged Sub-Q Infusion Set
MANUFACTURER	SIMS Deltec Inc.	SIMS Deltec Inc.	Micro Med, Inc.
CONFIGURATION			
needle length	½ inch	¾ inch	0.475 inch
needle angle	90°	30°	90°
gauge	27	27	27
tubing length	42 inches	30 inches	42 inches
winged needle	yes	yes	yes

V. INTENDED USE

The subject device is intended to facilitate subcutaneous infusion of fluids.

VI. SUMMARY OF STUDIES

A. **Functional Testing**

The subject device is designed to meet certain functional requirements related to tubing to needle and luer to tubing bond strength.

B. **Clinical Studies**

Clinical studies were not deemed necessary.

VII. CONCLUSION

Based upon the information provided above, the Deltec Subcutaneous Infusion Set is suitable for its intended use.