

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CliniCath™ IR Peripherally Inserted Central Catheters - K970269

January 22, 1997

JUN 26 1997

I. GENERAL INFORMATION

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

Contact Person: Lisa Stone
Manager, Regulatory Affairs
Tel. (612) 628-7224

Common/Usual Name: Peripherally Inserted Venous Catheters

Proprietary Name: CliniCath™ IR Peripherally Inserted Central Catheters

Equivalence Device Comparison: CliniCath™ Peripherally Inserted Venous Catheters
(manufactured by SIMS Deltec, Inc.)

Peripherally Inserted Central Venous Catheter Sets
(manufactured by Cook, Inc.)

II. DEVICE DESCRIPTION

The modified CliniCath™ IR Peripherally Inserted Central Catheters are similar in design and function to the current commercially available CliniCath™ Peripherally Inserted Venous Catheters.

The catheters are designed to permit repeated access to the venous system for the delivery of medications, fluids, and nutritional solutions, and for blood therapy and/or sampling.

The product consists of a single-lumen, radiopaque silicone catheter with preinserted catheter stiffening wire and attached flushing assembly. Catheters will be made available with and without the following accessories: introducer needle, guidewire, dilator/sheath assembly, syringe, tape measure, mini-scalpel and injection cap. Catheters will be provided in single- and multi-unit package configurations.

III. INTENDED USE OF DEVICE

The CliniCath™ IR Peripherally Inserted Central Catheter is used when patient therapy requires repeated venous access for intravenous injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

	CliniCath™ IR Peripherally Inserted Central Catheters	CliniCath™ Peripherally Inserted Catheters	Cook Peripherally Inserted Central Venous Catheter Sets
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	Cook, Inc.
INDICATION FOR USE	The CliniCath™ IR Peripherally Inserted Central Catheter is used when therapy requires repeated venous access for intravenous injection or infusion and/or venous blood sampling.	The CliniCath™ Peripherally Inserted Central Catheter is used when therapy requires repeated venous access for intravenous injection or infusion and/or venous blood sampling.	Peripherally Inserted Central Venous Catheter is suggested for: (1) Delivery of whole blood or blood products; (2) Drug administration; and (3) Blood sampling.
CATHETER INSERTION	Peripheral vein	Peripheral vein	Peripheral vein
CATHETER TIP PLACEMENT	Central	Peripheral/Central	Central
CATHETER MATERIAL	Radiopaque Silicone	Radiopaque Silicone	Radiopaque Silicone
AVAILABLE CATHETER SIZES	4 French (18 Gauge) 5 French (16 Gauge)	3 French (20 Gauge) 4 French (18 Gauge) 5 French (16 Gauge)	3 French 4 French 5 French
CATHETER O.D. AND I.D. (Nominal) 4 French 5 French	1.4 mm O.D. x 0.7 mm I.D. 1.7 mm O.D. x 1.0 mm I.D.	1.3 mm O.D. x 0.8 mm I.D. 1.7 mm O.D. x 1.0 mm I.D.	1.4 mm O.D. x 0.6 mm I.D. 1.7 mm O.D. x 0.9 mm I.D.
CATHETER LENGTH (Nominal)	65 cm	20 cm and 65 cm	50 cm and 60 cm
FLOW RATE (Nominal) (1 METER GRAVITY FLOW)	4 French (65 cm) 7 ml/min. ± 0.7 ml/min. 5 French (65 cm) 20 ml/min. ± 1.2 ml/min.	4 French (65 cm) 479 ml/hr 5 French (65 cm) 1420 ml/hr	4 French (60 cm) 270 ml/hr 5 French (60 cm) Sample not available for testing.

V. **SUMMARY OF STUDIES**

A. **Functional Testing**

In-vitro testing was conducted in accordance with the FDA "Guidance on Premarket Notification [510(k)] Submissions for Short- and Long-term Intravascular Catheters," dated March 1995.

Biocompatibility testing was conducted on the device.

B. **Clinical Studies**

Clinical studies were not deemed necessary regarding the CliniCath™ IR Peripherally Inserted Central Catheter due to its similarity in materials; design and function to current commercially available CliniCath™ Peripherally Inserted Venous Catheters.

C. **Conclusion Drawn from the Studies**

The results of the testing indicated that the CliniCath™ IR Peripherally Inserted Central Catheter functions according to specification and the materials used in the device are biocompatible. Therefore, the device is considered acceptable for human use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Stone
Manager, Regulatory Affairs
SIMS Deltec, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

JUN 26 1997

Re: K970269
Trade Name: Clini-Cath™ IR Peripherally Inserted
Catheter
Regulatory Class: Unclassified
Product Code: LJS
Dated: June 17, 1997
Received: June 18, 1997

Dear Ms. Stone:

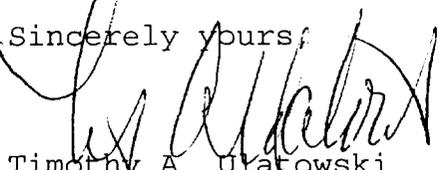
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Good Manufacturing Practice for Medical Devices: General

(GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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 at (301) 443-6597.

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

510(k) Number (if known): K 970269

Device Name: CliniCath™ IR Peripherally Inserted Central Catheters

Indications for Use:

"The CliniCath™ IR Peripherally Inserted Central Catheter is used when therapy requires repeated venous access for intravenous injection or infusion and/or venous blood sampling."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cuervo
(Division Sign-Off) K 970269
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 970269

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use