JAN 29 1999

K984055

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters

November 12, 1998

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® PolyFlow® Polyurethane Peripherally Inserted Catheters
Equivalence Device Comparison:	CliniCath® Peripherally Inserted Catheters (manufactured by SIMS Deltec, Inc.) BIOVUE Peripherally Inserted Catheters (manufactured by Johnson & Johnson Medical Inc.)

II. DEVICE DESCRIPTION

The modified CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters are similar in design and function to the current commercially available CliniCath® Peripherally Inserted Catheters.

The catheters are designed to permit repeated venous access for intravenous injection or infusion and/or venous blood sampling

The product consists of single- and dual-lumen, radiopaque polyurethane catheters with preinserted stylets, clamps, and attached stylet/flushing assemblies. Catheters will be made available with and without the following accessories: introducer needle, injection cap and procedural tray. Catheters will be provided in single- and multi-unit package configurations.

III. INTENDED USE OF DEVICE

The CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheter is used when therapy requires repeated venous access for intravenous injection or infusion and/or venous blood sampling.

IV. DEVICE COMPARISON

	CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters	CliniCath® Peripherally Inserted Catheters	BIOVUE Peripherally Inserted Catheters
MANUFACTURER	SIMS Deltec, Inc.	SIMS Deltec, Inc.	Johnson & Johnson Medical Inc.
INDICATION FOR USE	The CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheter is used when therapy requires repeated venous access for intravenous injection or infusion and/or venous blood sampling.	The CliniCath® Peripherally Inserted Catheter is used when therapy requires repeated venous access for intravenous injection or infusion and/or venous blood sampling.	BIOVUE Peripherally Inserted Catheters are designed for prolonged peripheral venous access for the infusion of IV therapy solutions and blood sampling.
CATHETER INSERTION	Peripheral vein	Peripheral vein	Peripheral vein
CATHETER TIP PLACEMENT	Peripheral/Central	Peripheral/Central	Peripheral/Central
CATHETER MATERIAL	Radiopaque Polyurethane	Radiopaque Silicone	Radiopaque Polyurethane
AVAILABLE CATHETER SIZES	Single-Lumen 2 French (24 Gauge) 3 French (20 Gauge) 4 French (18 Gauge) 5 French (16 Gauge) Dual-Lumen 4 French (18 Gauge) 5 French (16 Gauge)	Single-Lumen — 3 French (20 Gauge) 4 French (18 Gauge) 5 French (16 Gauge) — —	Single-Lumen 2 French (24 Gauge) 3 French (20 Gauge) 4 French (18 Gauge) — Dual-Lumen 4 French (18 Gauge) 5 French (16 Gauge)

— Catheter size is not commercially available

	CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters	CliniCath® Peripherally Inserted Catheters	BIOVUE Peripherally Inserted Catheters
CATHETER O.D. AND I.D. *(Nominal)*			
Single-Lumen			
2 French	0.7 mm O.D. x 0.4 mm I.D.	—	0.7 mm O.D. x 0.4 mm I.D.
3 French	1.0 mm O.D. x 0.5 mm I.D.	0.9 mm O.D. x 0.5 mm I.D.	1.0 mm O.D. x 0.6 mm I.D.
4 French	1.4 mm O.D. x 0.8 mm I.D.	1.3 mm O.D. x 0.8 mm I.D.	1.2 mm O.D. x 0.8 mm I.D.
5 French	1.7 mm O.D. x 1.0 mm I.D.	1.7 mm O.D. x 1.0 mm I.D.	—
Dual-Lumen			
4 French	1.4 mm O.D. x 0.8/0.6 mm I.D.	—	1.3 mm O.D. x *I.D. not noted*
5 French	1.7 mm O.D. x 0.9/0.8 mm I.D.	—	1.7 mm O.D. x *I.D. not noted*
CATHETER LENGTH *(Nominal)*	20 cm, 30 cm, 50 cm, and 65 cm	20 cm and 65 cm	20 cm, 30 cm, and 60 cm
FLOW RATE *(Nominal)*	DELTEC FLOW RATES: GRAVITY FLOW AT 1 METER	DELTEC FLOW RATES: GRAVITY FLOW AT 1 METER	J&J FLOW RATES: GRAVITY FLOW AT 48 INCHES
Single-Lumen			
2 French, 50 cm	37 ml/hr	—	—
2 French, 30 cm	62 ml/hr	—	66 ml/hr
2 French, 20 cm	89 ml/hr	—	—
3 French, 65 cm	123 ml/hr	68 ml/hr	—
3 French, 60 cm	—	—	150 ml/hr
3 French, 20 cm	362 ml/hr	227 ml/hr	270 ml/hr
4 French, 65 cm	659 ml/hr	479 ml/hr	—
4 French, 60 cm	—	—	570 ml/hr
4 French, 20 cm	1505 ml/hr	>999 ml/hr	960 ml/hr
5 French, 65 cm	1444 ml/hr	>999 ml/hr	—
5 French, 20 cm	3020 ml/hr	>999 ml/hr	—
Dual-Lumen			
4 French, 60 cm	—	—	150 ml/hr (each lumen)
4 French, 65 cm	224 ml/hr (lg lumen) 123 ml/hr (sm lumen)	—	—
4 French, 20 cm	611 ml/hr (lg lumen) 322 ml/hr (sm lumen)	—	240 ml/hr (each lumen)
5 French, 60 cm	—	—	540 ml/hr (each lumen)
5 French, 65 cm	660 ml/hr (lg lumen) 424 ml/hr (sm lumen)	—	—
5 French, 20 cm	1606 ml/hr (lg lumen) 1096 ml/hr (sm lumen)	—	—

— Catheter size is not commercially available

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® PolyFlow® Polyurethane Peripherally Inserted Catheter due to its similarity in design and function to current commercially available peripherally inserted catheters.

C. Conclusion Drawn from the Studies

The results of the testing indicated that the CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters function according to specification and the materials used in the device are biocompatible. Therefore, the device is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1999

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

Re: K984055
Trade Name: CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters
Regulatory Class: II
Product Code: FOZ
Dated: November 12, 1998
Received: November 13, 1998

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

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): K984055

Device Name: CliniCath® PolyFlow® Polyurethane Peripherally Inserted Catheters

Indications for Use:

"The CliniCath® PolyFlow® Polyurethane Peripherally Inserted 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)

(Division Sign-Off) Brenda Bolden
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984055

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)