K972264

SEP 15 1997

SUMMARY OF SAFETY AND EFFICACY

A. The submitter's name, address, telephone number, contact person, and date of preparation.

Submitted by Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, UT 84070.
Contact: C. J. Welle. Telephone: 801-565-2535. Prepared: June 11, 1997.

B. The name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name.

Name: Intravascular Catheter
Brand: FIRST MIDCATH™
Common Name: Midline Catheter with Dual Lumens
Classification Name: Intravascular Catheter (80 FOZ)

C. An identification of the predicate or legally marketed device to which substantial equivalence is claimed:

Predicate Device: The Becton Dickinson Infusion Therapy Systems Inc. FIRST MIDCATH™ brand catheters.

D. A description of the device that is the subject of the Premarket Notification submission.

The subject catheter is a short term, single use, intravascular catheter of various French sizes and lengths which is designed to provide access to large veins such as the baslic or cephalic veins. It is inserted into the vascular system through a spittable introducer catheter.

E. Statement of intended use of the device.

The intended use is to provide access to the vascular system to sample blood or administer drug solutions, blood products, or other fluids intravenously.

F. A statement of how the technological characteristics compare to those of the predicate or legally marketed device identified in section C above.

The proposed catheter differs from the FIRST MIDCATH™ brand catheter in that the stylet and labeling have been modified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1997

Mr. Charles Welle
Manager, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems
9450 South State Street
Sandy, Utah 84070

Re: K972264
Trade Name: First MIDCATH™ Catheter with Dual Lumens
Regulatory Class: II
Product Code: FOZ
Dated: June 11, 1997
Received: June 17, 1997

Dear Mr. Welle:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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, 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 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 current Good Manufacturing Practice requirement, as set forth in the

Quality System Regulation for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

In addition, we have determined that your device kit contains Iodophor swabsticks, alcohol swabsticks, and skin protectant swabsticks which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0063

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 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

June 11, 1996

INDICATIONS FOR USE

510(k) Number: K 972264

Device Name: FIRST MIDCATH™ Catheter with Dual Lumens

Indications for Use: To sample blood or administer drug solutions, blood products, and other fluids intravenously. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy.

[redacted]
(Division Sign-Off)
Dental, Infection Control,
Hospital Devices

Patricia Cusenza
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 972264

Concurrence of CDRH, Office of Device Evaluation (ODE)

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