Becton Dickinson Infusion Therapy Systems
9450 South State Street
Sandy, Utah 84070
(801) 565-2300
(801) 565-2740 Fax

FEB 2 6 1998

K974764

BECTON DICKINSON

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: December 18, 1997.

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

Name: Introducer Catheter
Brand: INTROSYTE™ PRECISION INTRODUCER
Common Name: Introducer Catheter
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 INTROSYTE™ brand, INSYTE® brand and SPLIT SECOND® brand introducer catheters and the Teleflex, Inc. Percutaneous Introducer Set.

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

The subject catheter is a short term, single use introducer catheter of various gauges and lengths which is designed to split and peel away following use. It is inserted into the vascular system over a needle.

E. Statement of intended use of the device.

The intended use is to facilitate the placement of other devices such as guidewires, central venous catheters, peripherally inserted central venous catheters, and midline catheters in the vascular system.

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 INSYTE® brand introducer catheter in that it is splittable; however, the intended use is the same. It is similar to the INTROSYTE™ brand introducer, the SPLIT SECOND® brand introducer catheter and the Teleflex, Inc. Percutaneous Introducer Set in that all are splittable and all are introducer catheters.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 1998

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

Re: K974764
Trade Name: INTROSYTE™ Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 18, 1997
Received: December 19, 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 (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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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,

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

Enclosure

CELEBRATING THE FIRST ONE HUNDRED: 1897-1997

BECTON DICKINSON

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December 18, 1997

INDICATIONS FOR USE

510(k) Number: K 974764

Device Name: **INTROSYTE™ Catheters**

Indications for Use: **TO FACILITATE THE PLACEMENT OF DEVICES SUCH AS GUIDEWIRES, INDWELLING CENTRAL VENOUS CATHETERS, PERIPHERALLY INSERTED CENTRAL VENOUS CATHETERS, AND MIDLINE CATHETERS INTO THE VASCULAR SYSTEM.**

Patricia Cuesta

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974764
Prescription Use: X OR Over-The -Counter Use: _____
(Per 21 CFR 801.109)