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K013073

NOV 0 8 2001

BD

Indispensable to human health

Premarket Notification [510(k)] Summary of Safety and Effectiveness for Insyte™, Angiocath™, Insyte™ Autoguard™, Angiocath™ Autoguard™, Autoguard™ Pro, Intima™, and Saf-T-Intima™ IV Catheters

Submitter:	Becton Dickinson Infusion Therapy Systems Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Leslie Wood, Manager, Regulatory Affairs
Telephone Number:	(801) 565-2504
FAX Number:	(801) 565-2749
Date Summary Prepared:	August 9, 2001
Trade Names:	Insyte™ IV Catheter; Angiocath™ IV Catheter; Insyte™ Autoguard™ IV Catheter; Angiocath™ Autoguard™ IV Catheter; Autoguard™ Pro IV Catheter; Intima™ IV Catheter; and Saf-T-Intima™ IV Catheter
Common Name:	Peripheral Intravascular Catheter or IV Catheter
Classification Name:	Intravascular Catheter
Predicate Devices:	Same as trade names listed above.

Product Descriptions:

The products identified in this 510(k) notification include both standard catheters and catheters with a needle-shielding feature. The catheters listed have either a FEP polymer or Vialon material catheter. All have a luer-locking adapters to which an IV line or accessories may be attached.

Intended Use:

An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously.

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Technological Characteristics Comparison:

The catheter design and technological characteristics have not changed. The lubrication systems used have been modified to make the manufacturing process 'ozone friendly.'

Nonclinical Tests Support Substantial Equivalence:

Side-by-side testing of modified and unmodified devices was conducted to compare the following attributes: penetration, tip adhesion and catheter / adapter separation force.

Conclusions from Nonclinical Tests:

Data have been provided to demonstrate that product performance and biocompatibility are substantially equivalent between the modified and unmodified devices.

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 premarket 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

NOV 0 8 2001

Ms. Leslie Wood
Manager, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems, Incorporated
9450 South State Street
Sandy, Utah 84070

Re: K013073
Trade/Device Name: Insyte™, Intravascular Catheter Angiocath™, Intravascular Catheter Insyte™, Autoguard™, Intravascular Catheter Angiocath™, Autoguard™, Intravascular Catheter Autoguard™, Pro Intravascular Catheter Intima™, Intravascular Catheter Saf-T-Intima™, Intravascular Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: September 12, 2001
Received: September 14, 2001

Dear Ms. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

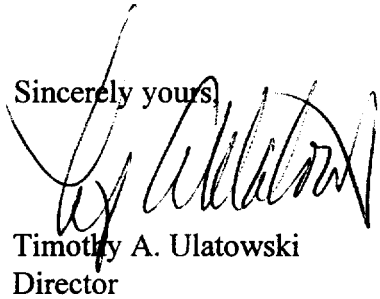
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/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

K013073

Becton Dickinson Infusion Therapy Systems Inc.
Sandy, UT 84070

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INDICATIONS FOR USE

Device Name: Insyte™ Intravascular Catheter
Angiocath™ Intravascular Catheter
Insyte™ Autoguard™ Intravascular Catheter
Angiocath™ Autoguard™ Intravascular Catheter
Autoguard™ Pro Intravascular Catheter
Intima™ Intravascular Catheter
Saf-T-Intima™ Intravascular Catheter

As provided in 21 CFR 880.5200, an intravascular catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The Counter Use: _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013073