



Food and Drug Administration  
10903 New Hampshire Avenue  
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July 27, 2015

Becton Dickinson Infusion Therapy Systems, Incorporated  
c/o Mr. Mark Job  
Regulatory Technology Services, Inc.  
1394 25<sup>th</sup> Street, NW  
Buffalo, MN 55313

Re: K151698

Trade/Device Name: BD Angiocath™ and Insyte™ Catheters  
Regulation Number: 21 CFR 880.5200  
Regulation Name: Intravascular Catheter  
Regulatory Class: II  
Product Code: FOZ  
Dated: July 15, 2015  
Received: July 16, 2015

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151698

Device Name

BD Angiocath IV Catheter and Insyte IV Catheter

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**Section 5****510(k) Summary****510(k) Summary****21 CFR §807.92****BD Angiocath™ and Insyte™ IV Catheters**

<b>Submitter Information</b>	Submitter Name:	Becton Dickinson Infusion Therapy Systems Inc.
	Submitter Address:	9450 South State Street Sandy, UT 84070
	Contact Person:	Henry Boland Senior Regulatory Affairs Specialist Phone: 801.565.2550 Fax: 801.304.3963 Email: henry_boland@bd.com
	Date of Preparation:	14 May 2015
<b>Subject Devices</b>	Trade Name:	BD Angiocath™ IV Catheter
	Common Name:	Peripheral Intravascular or IV Catheter
	Classification Name:	FOZ - Intravascular Catheter
	CFR Reference:	21 CFR 880.5200 - Class II
	Classification Panel:	General Hospital
	Trade Name:	BD Insyte™ IV Catheter
	Common Name:	Peripheral Intravascular or IV Catheter
	Classification Name:	FOZ - Intravascular Catheter
	CFR Reference:	21 CFR 880.5200 - Class II
	Classification Panel:	General Hospital
<b>Predicate Devices</b>	Trade Name:	BD Angiocath™ and Insyte™ IV Catheter
	510(k) Reference:	K013800
	Common Name:	Peripheral Intravascular or IV Catheter
	Classification Name:	FOZ - Intravascular Catheter
	CFR Reference:	21 CFR 880.5200 - Class II
	Classification Panel:	General Hospital
<b>Device Description</b>	Insyte™, Insyte-N™, and Insyte-W™ are available in 14-24 gauge and are made of BD Vialon™ Material. Angiocath™ is available in 14-24 gauge and is made of FEP Polymer material.	

**Indications for Use**

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.

**Technological Characteristics**

Technological characteristics of the subject devices are equivalent to the predicates. The BD Angiocath™ and Insyte™ IV Catheters achieve their intended use based on the same technology and principles of operation. The subject devices have been modified from the predicate devices as listed below. The results of design verification demonstrate that these changes are substantially equivalent to the predicate devices. All other aspects of the subject device are identical to those of the predicate device.

- Change to lubricants used in the assembly on the device

Attribute	SUBJECT DEVICE		PREDICATE DEVICE
<b>Indications for Use</b>	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.		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.
<b>Design</b>	A fluorinated ethylene propylene (FEP) or polyurethane peripheral IV catheter		A fluorinated ethylene propylene (FEP) or polyurethane peripheral IV catheter
<b>Materials</b>	<b>Component</b>	<b>Subject Device</b>	<b>Predicate Device</b>
	<u>Catheter Tubing</u>	<u>Angiocath™ IV Catheter</u> Fluorinated ethylene propylene (FEP)  <u>Insyte™ IV Catheter</u> BD Vialon™ polyurethane	<u>Angiocath™ IV Catheter</u> Fluorinated ethylene propylene (FEP)  <u>Insyte™ IV Catheter</u> BD Vialon™ polyurethane
	<u>Catheter Hub</u>	Polypropylene	Polypropylene
	<u>Metal Wedge</u>	Stainless Steel	Stainless Steel
	<u>Needle</u>	Stainless Steel	Stainless Steel
	<u>Needle Hub</u>	<u>Angiocath™ IV Catheter</u> Propionate  <u>Insyte™ IV Catheter</u> Propionate	<u>Angiocath™ IV Catheter</u> Propionate  <u>Insyte™ IV Catheter</u> Propionate
	<u>Needle Cover</u>	Polypropylene	Polypropylene

<b>Materials (cont.)</b>	<u>Vent Plug</u>	<u>Angiocath™ IV Catheter</u> Polyethylene	<u>Angiocath™ IV Catheter</u> Polyethylene
		<u>Insyte™ IV Catheter</u> Polypropylene with filter	<u>Insyte™ IV Catheter</u> Polypropylene with filter
	<u>Catheter Tipping Lubricant</u>	Polydimethylsiloxane-based Lubricant	Polydimethylsiloxane-based Lubricant
	<u>Catheter Lubricant</u>	Polydimethylsiloxane-based Lubricant	Polydimethylsiloxane-based Lubricant
	<u>Wedge Lubricant</u>	Polydimethylsiloxane-based Lubricant	Polydimethylsiloxane-based Lubricant
	<u>Needle (Cannula) Lubricant</u>	Two-Part Polydimethylsiloxane-based Lubricant	Single-Part Polydimethylsiloxane-based Lubricant
<b>Physical / Mechanical Specifications</b>	<b>SUBJECT DEVICES</b>		<b>PREDICATE DEVICES</b>
	<u>Angiocath™ IV Catheter</u> Catheter Diameters: 14G, 16G, 18G, 20G, 22G, 24G Catheter Lengths: 0.75", 1.00", 1.16", 1.88" Non-winged only		<u>Angiocath™ IV Catheter</u> Catheter Diameters: 14G, 16G, 18G, 20G, 22G, 24G Catheter Lengths: 0.75", 1.00", 1.16", 1.88" Non-winged only
	<u>Insyte™ IV Catheter</u> Catheter Diameters: 14G, 16G, 18G, 20G, 22G, 24G Catheter Lengths: 0.56", 0.75", 1.00", 1.16", 1.77", 1.88" Winged or Non-winged		<u>Insyte™ IV Catheter</u> Catheter Diameters: 14G, 16 G, 18G, 20G, 22G, 24G Catheter Lengths: 0.56", 0.75", 1.00", 1.16", 1.77", 1.88" Winged or Non-winged

**Summary of Performance Tests**

Pursuant to 21 CFR 820.30, Design Controls, design verification tests were performed based on the risk analysis, and the results of these tests demonstrate that the BD Angiocath™ and Insyte™ IV Catheters are substantially equivalent to the predicate devices. Design verification testing included the following:

Characteristic / Test Performed	Test Method	Results
<b>Biocompatibility</b>	Per ISO 10993-1	Pass
<b>Liquid leakage</b>	Per ISO 594-1, -2	Pass
<b>Air leakage</b>	Per ISO 594-1, -2	Pass
<b>Separation force</b>	Per ISO 594-1, -2	Pass
<b>Stress cracking</b>	Per ISO 594-1, -2	Pass

<b>Unscrewing torque</b>	Per ISO 594-2	Pass
<b>Ease of assembly</b>	Per ISO 594-2	Pass
<b>Resistance to overriding</b>	Per ISO 594-2	Pass
<b>General</b>	Per ISO 10555-1	Pass
<b>Radio-detectability</b>	Per ISO 10555-1	Pass
<b>Biocompatibility</b>	Per ISO 10555-1	Pass
<b>Surface</b>	Per ISO 10555-1	Pass
<b>Corrosion resistance</b>	Per ISO 10555-1	Pass
<b>Peak tensile force</b>	Per ISO 10555-1	Pass
<b>Freedom from leakage</b>	Per ISO 10555-1	Pass
<b>Hubs</b>	Per ISO 10555-1	Pass
<b>Flowrate</b>	Per ISO 10555-1	Pass
<b>Power injection</b>	Per ISO 10555-1	Pass
<b>Side holes</b>	Per ISO 10555-1	NA
<b>Distal tip</b>	Per ISO 10555-1	Pass
<b>Color code</b>	Per ISO 10555-5	Pass
<b>Catheter unit</b>	Per ISO 10555-5	Pass
<b>Needle point</b>	Per ISO 10555-5	Pass
<b>Needle hub</b>	Per ISO 10555-5	Pass
<b>Strength of union between needle hub and needle tube</b>	Per ISO 10555-5	Pass
<b>Vent fitting</b>	Per ISO 10555-5	Pass
<b>Needle (Cannula) penetration force</b>	Internal design input, identical to predicate	Pass
<b>Catheter penetration force</b>	Internal design input, identical to predicate	Pass
<b>Catheter average drag force</b>	Internal design input, identical to predicate	Pass

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<b>Minimal catheter and cannula tip adhesion</b>	Internal design input, identical to predicate	Pass
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**Summary of Substantial Equivalence**

Based on the indications for use, technological characteristics, and performance testing, the subject BD Angiocath™ and Insyte™ IV Catheters meet all predetermined requirements in accordance with 21 CFR 820.30, Design Controls, and demonstrates that the subject devices are substantially equivalent to the predicate devices.

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