

4/9/99

BECTON DICKINSON AND COMPANY

K984059

**BECTON
DICKINSON**

Becton Dickinson Infusion Therapy
9450 South State Street
Sandy, Utah 84070
Tel (801) 565-2535
Fax (801) 565-2749

510(k) NOTIFICATION

SUMMARY OF SAFETY AND EFFICACY

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

Submitted by Becton Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1880.

Contact: C. J. Welle, Becton Dickinson Infusion Therapy, 9450 South State Street, Sandy, UT 84070. Telephone: 801-565-2535.

Prepared: November 9, 1998.

- 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: ANGIOCATH® AUTOGUARD™ and INSYTE® AUTOGUARD™ catheters

Common Name: Intravascular 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 ANGIOCATH® AUTOGUARD™ and INSYTE® AUTOGUARD™ 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 gauges and lengths which is designed to provide access to the vascular system. The catheter unit is provided with a mechanism which allows the needle to be shielded following placement of the catheter.

- E. Statement of intended use of the device.

As provided at 21 CFR 880.5200, the intended use is to provide access to the vascular system to sample blood, monitor blood pressure, or administer fluids intravenously.

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- 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from the ANGIOCATH® AUTOGUARD™ and INSYTE® AUTOGUARD™ brand catheters in that the mechanism by which the needle is withdrawn into the shield has been modified.

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

APR 9 1999

Mr. Charles J. Welle
Becton Dickinson & Company
9450 South State Street
Sandy, Utah 84070

Re: K984059
Trade Name: ANGIOCATH® AUTOGUARD® Catheter, INSYTE®
AUTOGUARD® Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 28, 1999
Received: February 1, 1999

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.

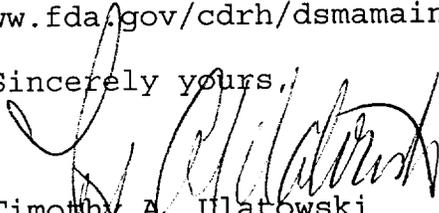
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

Page 2 - Mr. Welle

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) NOTIFICATION

March 29, 1998

INDICATIONS FOR USE

510(k) Number: K984059

Device Name: ANGIOCATH® AUTOGUARD™ and INSYTE®
AUTOGUARD™ Catheters

Indications for Use: As indicated in 21 CFR 880.5200, to sample blood, monitor blood pressure, or administer 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.

The ANGIOCATH® AUTOGUARD™ and INSYTE® AUTOGUARD™ catheters provide a shielding mechanism intended to reduce the incidence of accidental needle sticks. When the activation button is depressed by the clinician, the needle is withdrawn into the shield.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X
(Per 21 CFR 801.109)

OR

Over-The -Counter Use: _____

Patricia Cicerone
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 984059