

K971339

DEC 24 1997

SUMMARY OF SAFETY AND EFFICACY

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

Submitted by Becton Dickinson Vascular Access, 9450 South State Street, Sandy, UT 84070.

Contact: C. J. Welle. Telephone: 801-565-2535. Prepared: April 10, 1997.

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

Name: Diagnostic Intravascular Catheter

Brand: INSYTE®, INSYTE-W®, and INSYTE® AUTOGUARD™ II Catheters

Common Name: I.V. Catheter

Classification Name: Diagnostic Intravascular Catheter (74DQO)

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

Predicate Device: The Becton Dickinson Vascular Access INSYTE®, INSYTE-W®, 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, diagnostic intravascular catheter of various gauges and lengths which is designed to provide access to the vascular system. It is a radiopaque, VIALON® catheter for which the labeling sets forth the conditions of use with power injectors.

- E. Statement of intended use of the device.

The intended use is to provide access to the vascular system to monitor blood pressure, to sample blood or introduce substances into the heart and vessels. The catheters may be used with power injectors for which the maximum rated pressure is 300 psi.

- 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®, INSYTE-W®, and INSYTE® AUTOGUARD™ brand catheters currently marketed in that the labeling clarifies the suitability of the catheters for use with power injectors.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 1997

Mr. Charles J. Welle
Manager, Regulatory Affairs
Becton Dickinson Vascular Access, Incorporated
9450 South State Street
Sandy, Utah 84070

Re: K971339
Trade Name: INSYTE®, INSYTE-W® and INSYTE® AUTOGUARD™
Catheters
Regulatory Class: II
Product Code: FOZ
Dated: September 22, 1997
Received: September 30, 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

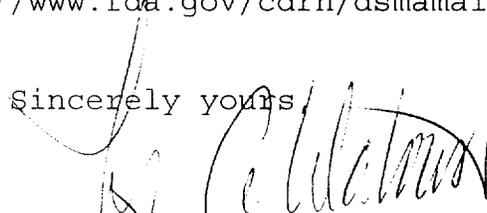
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

April 10, 1997

INDICATIONS FOR USE

510(k) Number: K 971339

Device Name: INSYTE®, INSYTE-W®, and INSYTE® AUTOGUARD™ Catheters

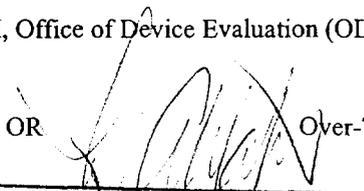
Indications for Use: As indicated in 21 CFR 870.1200, to sample blood, to monitor blood pressure, or to introduce substances into the heart and vessels . These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The catheters may be used with power injectors for which the maximum rated pressure is 300 psi.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X
(Per 21 CFR 801.109)

OR

Over-The -Counter Use: _____


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971339

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