AUG 20 1999

510(k) Summary

K990236

Date	August 16, 1999
Contact	Linda G. Hill Sr. Project Manager, Regulatory Affairs Johnson & Johnson Medical, Division of Ethicon, Inc. 2500 East Arbrook Boulevard Arlington, TX 76014-3631 Telephone: (817)262-4791 Telefax: (817)262-5369
Trade Names	• JELCO*, JELCO*-W and JELCO* PLUS Intravascular (I.V.) Catheters • CATHLON* I.V. Catheters • OPTIVA* I.V. Catheters • PROTECTIV*, PROTECTIV*-W, PROTECTIV* PLUS and PROTECTIV* PLUS-W I.V. Catheter Safety Systems
Common Name	Intravascular Catheter
Classification	Intravascular Catheters have been classified by the General Hospital and Personal Use Devices as Class II under 21 CFR Part 880.5200. The product code assigned to these devices is FOZ.
Device Description	Intravascular catheters are single use devices which provide access to veins or arteries.

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*Trademark

INSYTE, AUTOGUARD and VIALON are trademarks of Becton-Dickinson, Inc.

510(k) Summary, Continued

Indications

The intravascular catheters and safety systems are designed for single use. A properly placed intravascular catheter provides access to a vein or artery. 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. 16 to 24 gauge catheters may be used with power injectors for which the maximum rated pressure is 300 psi.

Contra-indications

The devices are not designed, sold or intended for use except as indicated.

Predicate Devices

The intravascular catheters with the proposed additional indication for use (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. 16 to 24 gauge catheters may be used with power injectors for which the maximum rated pressure is 300 psi) are substantially equivalent to the currently-marketed catheters:

- JELCO*, JELCO*-W, and JELCO* PLUS, I.V. Catheters
- CATHLON* I.V. Catheters
- OPTIVA* I.V. Catheters
- PROTECTIV*,PROTECTIV*-W, PROTECTIV* PLUS, and PROTECTIV* PLUS-W I.V. Catheter Safety Systems
- Becton-Dickinson INSYTE®, INSYTE®-w AND INSYTE® AUTOGUARD™ I.V. CATHETERS

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*Trademark

510(k) Summary, Continued

Technological Characteristics Comparison	The Johnson & Johnson Medical (JJM) catheters have the same technological characteristics as the predicate devices. The catheters with the proposed additional indication for use are identical to the currently-marketed catheters. No changes (materials, specifications, manufacturing and sterilization processes) have been made to the currently-marketed catheters. The catheters differ from the currently-marketed JJM catheters only in the instructions for use which now include use of the 16 to 24 gauge catheters with power injectors for which the maximum rated pressure is 300 psi. The use with power injectors claim is the same as the Becton-Dickinson catheters claim for use with power injectors.
Performance Data	Bench data demonstrates that the 16 to 24 gauge JJM catheters are appropriate for use with power injectors rated for a maximum of 300 psi.
Conclusions	In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based upon the information provided in this premarket notification, Johnson & Johnson Medical, Division of Ethicon, Inc., concludes that the modified devices are safe, effective and substantially equivalent to the predicate devices.
Other Information	Johnson & Johnson Medical will update and include in this summary any other information deemed reasonable necessary by the FDA.

*Trademark

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1999

Ms. Linda G. Hill
Sr. Project Manager, regulatory Affairs
Johnson & Johnson Medical, Division Of Ethicon, Incorporated
2500 East Arbrook Boulevard
Arlington Texas 76014-3631

Re: K990236
Trade Name: Modification Of Jelco*, Jelco*-W And Jelco* Plus I.V. Catheters
Regulatory Class: II
Product Code: FOZ
Dated: July 01, 1999
Received: July 02, 1999

Dear Ms. Hill:

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 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 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) 594-4692. 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

Indications for Use

510(k) Number: K990236

Device Name: JELCO*, CATHLON* AND OPTIVA* I.V. Catheters and PROTECTIV* I.V. Catheter Safety Systems

Indications for Use:

Johnson & Johnson Medical Intravascular Catheters are designed for single use. A properly placed I. V. catheter provides access to a vein or artery. 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. 16 to 24 gauge catheters may be used with power injectors for which the maximum rated pressure is 300 psi.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

*Trademark

Patricia Cucenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990236