

APR 28 1998

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
for I.V. Catheter System**

**Johnson & Johnson Medical
2500 Arbrook Boulevard
P.O. Box 90130
Arlington, Texas 76004-3130**

Date: February 6, 1998

1. REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

2. CONTACT PERSON

Linda G. Hill
(817) 784-4791

3. NAME OF MEDICAL DEVICE:

Classification Name: Catheter, Intravascular, Short Term
Common/Usual Name: I.V. Catheter
Proprietary Name: To be determined

4. DEVICE CLASSIFICATION:

The General Hospital Panel has classified Intravascular Catheters (21 CFR 880.5200) into Class II, Special Controls under section 513 of the Act.

5. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The *I.V. Catheter System* is substantially equivalent to JJM's existing CRITIKON* OCR I.V. Catheter and to Bio-Plexus' existing Punctur-Guard® Blood Collection Needle. See attached Comparison Matrix, Table 1.

6. INTENDED USE:

The *I.V. Catheter System* is designed to gain access to and deliver a short term (<30 days) intravascular catheter into the patient's vascular system to sample blood, monitor blood pressure, or administer fluids.

510(k) SUMMARY (continued)**7. DESCRIPTION OF DEVICE:**

The *I.V. Catheter System* contains a short term intravascular catheter and a catheter introducer. The intravascular catheter consists of a slender catheter tube and a catheter hub. The catheter introducer consists of a housing that contains a flash chamber, a flash plug, a stainless steel needle and a needle safety mechanism. The *I.V. Catheter System* is designed to reduce the risk of accidental needlesticks.

8. SUMMARY OF MATERIAL TESTING:

The *I.V. Catheter System* meets ISO 10993-1 requirements for material safety and biocompatibility. The introducer needle meets the requirements of ISO 10555-5. The I.V. catheter has previously received FDA clearance.

9. SUMMARY OF SIMULATED USE STUDY:

There were 50 participants and a total of 500 *I.V. Catheter Systems* were successfully inserted and evaluated. No sharps injuries or failures of the protective feature occurred.

The results of this study support the claim that the *I.V. Catheter System* can reduce the risk of accidental needlestick injuries. The positive responses from the 50 participants regarding insertion and use characteristics indicate the the *I.V. Catheter System* is intuitive in nature, requires little or no change in usual technique, and meets customer requirements.

10. CONCLUSION:

The material testing and simulated use data indicate that the *I.V. Catheter System* is safe and effective for its intended use.

TABLE 1. COMPARISON MATRIX

A comparison matrix for various factors is presented below for the *I.V. Catheter System* in comparison with CRITIKON* OCR I.V. Catheter and Punctur-Guard® Blood Collection Needle.

Factor	<i>I.V. Catheter System</i>	CRITIKON* OCR I.V. Catheter	Punctur-Guard® Blood Collection Needle
Intended Use and Claims			
Same Intended Use	Yes	Yes	No
Venipuncture Device	Yes	Yes	Yes
Sharps Injury Prevention Feature	Yes	No	Yes
Reduces Risk of Accidental Needlesticks	Yes	No	Yes
Delivers Short Term Intravascular Catheter	Yes	Yes	No
Conventional Venipuncture Technique	Yes	Yes	Yes
Radiopaque Catheter	Yes	Yes	Not Applicable
Catheter Insertion Technique	1-handed or 2-handed	1-handed or 2-handed	Not Applicable
Technological Features			
Same Technological Features	Yes	No	Yes
Sharps Injury Prevention Mechanism	Passive	None	Active
Self-Blunting Needle	Yes	No	Yes
Blunt Locks in Place	Yes	Not Applicable	Yes
Sharps Injury Prevention Feature Remains Activated During Disposal	Yes	Not Applicable	Yes
Flashback Visualization	Yes	Yes	Yes
Removable Flashplug and Luer Adapter	Yes	Yes	Not Applicable

Factor	<i>I.V. Catheter System</i>	CRITIKON* OCR I.V. Catheter	Punctur-Guard® Blood Collection Needle
Specifications			
Multiple Gauge Sizes and Needle Lengths	Yes	Yes	Yes
EtO Sterilized	Yes	Yes	Yes
Other			
Sharps Injury Prevention Feature is an Integral Part of Device	Yes	Not Applicable	Yes
Minimal User Training	Yes	Yes	Yes

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1998

Ms. Linda G. Hill
Sr. Manager, Regulatory Affairs
Johnson & Johnson Medical
2500 Arbrook Boulevard
Arlington, Texas 76004-3130

Re: K980493
Trade Name: I.V. Catheter System
Regulatory Class: II
Product Code: FOZ
Dated: February 6, 1998
Received: February 9, 1998

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

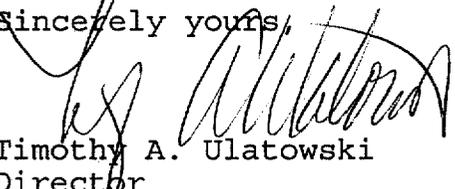
Page 2 - Ms. Hill

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

Applicant

Johnson & Johnson Medical
P.O. Box 90130
Arlington, Texas 76004-3130, USA

510(k) Number

This is a new submission and FDA has not assigned a number at this time

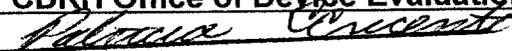
Device Name

I.V. Catheter System

Indications for Use

A properly placed I.V. catheter provides access to a vein or artery. The *I.V. Catheter System* is designed for single use and has a needlestick protection feature. The risk of accidental needlesticks is reduced by a self-blunting needle system activated automatically as the catheter is threaded into the vessel.

(Please do not write below this line-Continue on another page if needed)
Concurrence of CDRH Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 11 980423

Prescription Use OR Over-the-Counter
Per 21 CFR 801.109
(Optional Format 1-2-96)