

K964868

MAY 20 1997



**510(k) Summary of Safety and Effectiveness**

**2.9F Cragg-McNamara™ Valved Infusion Catheter**

**General Information**

<b>Classification</b>	Class II
<b>Trade Name</b>	2.9F Cragg-McNamara™ Valved Infusion Catheter
<b>Generic Name</b>	Infusion Catheter
<b>Submitter</b>	Micro Therapeutics, Inc. 1062-F Calle Negocio San Clemente, CA 92673
<b>Contact</b>	Linda D'Abate Clinical and Regulatory Affairs

**Predicate Devices**

Micro Therapeutics Infusion Catheters (K940634, October 14, 1994)

**Device Description**

The 2.9F Cragg-McNamara™ Valved Infusion Catheter is a single lumen plastic catheter suitable for infusion of physician-specified pharmacological agents or contrast media through its proximal luer adapter to infusion holes circumferentially placed in the distal portion of the catheter. The device is designed to be placed over a guide wire into the general vasculature. The device will be available in various catheter and infusion lengths.

The 2.9F Cragg-McNamara™ Valved Infusion Catheter utilizes a plastic valve at the tip which will allow effective transmission of infusate through the side holes by effectively occluding infusion out the catheter. As a guide wire is introduced, the valve opens to permit smooth passage of the guide wire and closes again as the guide wire is removed. The recommended maximum guide wire OD is 0.018 inch.

The 2.9F Cragg-McNamara™ Valved Infusion Catheter has two radiopaque markers that define fluoroscopically the location of the exit holes.

The method of construction and materials used for these infusion catheters are substantially equivalent to previous infusion catheter products.

### **Intended Use**

The 2.9F Cragg-McNamara™ Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacological agents or contrast media into the general vasculature.

### **Testing**

Biocompatibility testing was performed on the 2.9F Cragg-McNamara™ Valved Infusion Catheter in Tests in accordance with the International Standard for the Biological Evaluation of Medical Devices, Part 1: Guidance on Selection of Tests (ISO 10993-1:1992(E)) to establish that the materials and processes used in the manufacture of the device met the qualifications for short term use in the vascular system. Results of the tests showed that the device passed biocompatibility testing and is suitable for its application.

Physical testing of the product included: dimensional inspection, catheter tensile strength tests, static and dynamic burst pressure tests, flow rate test, and performance under simulated conditions. All testing of the product yielded acceptable results.

### **Summary of Substantial Equivalence**

The 2.9F Cragg-McNamara™ Valved Infusion Catheter is constructed of the same or substantially equivalent materials as the Micro Therapeutics Infusion Catheters and other legally marketed infusion catheters. The sizes and configurations available along with the packaging and sterilization methods are also equivalent.

The clinical indications for use are identical to the predicate devices.

Therefore, due to the similarity of materials to other infusion catheters, the test results and the identical indications for use to other infusion catheters, Micro Therapeutics believes these products do not raise any new safety or effectiveness issues.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 20 1997

Ms. Joy Tan  
Regulatory Affairs  
Micro Therapeutics, Inc.  
1062-F Calle Negocio  
San Clemente, California 92673

Re: K964868  
2.9F Cragg-McNamara™ Valved Infusion Catheter  
Regulatory Class: II (two)  
Product Code: KRA  
Dated: February 19, 1997  
Received: February 20, 1997

Dear Ms. Tan:

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) 594-4648. 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 at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): **K964868**

Device Name: **2.9F Cragg-McNamara™ Valved Infusion Catheter**

Indications for Use:

The 2.9F Cragg-McNamara™ Valved Infusion Catheter is intended to be used for the controlled selective infusion of physician specified pharmacological agents and radiopaque contrast media into the general vasculature. It is not intended for coronary, neurological, pediatric or neonatal use.

*Ta A R*

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

510(k) Number K964868

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   ✓    
(Per 21 CFR 801.109)

OR

Over the Counter Use