

JUL 23 1999

Attachment 4**1) 510(k) summary****510(k) Summary****SAFETY AND EFFECTIVENESS SUMMARY**

This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by Name/Address:	Chester McCoy Regulatory Affairs Engineer Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 253-1600 ext. 404 (801) 253-1684 fax
Contact Person:	Same as above
Date Summary Prepared:	June 4, 1999
Device Name:	4 French FOUNTAIN™ Catheter and Occluding/Guide Wire
Common Name:	Infusion Catheter and Occluding/Guide Wire
Trade Name:	FOUNTAIN™ Infusion System
Classification (if known):	Intravascular Catheter
Predicate Device:	5 French FOUNTAIN™ Infusion Catheter and Occluding Guide Wire (K974067) & K991619 Fountain Infusion System
Device Description:	

This device is a 4 French infusion catheter and system.

Intended Use:

The Fountain™ Infusion System is intended to administer infusions of various therapeutic solutions into the peripheral vasculature of a patient.

Device Use:

The Fountain™ Infusion Catheter will be placed in the peripheral vasculature of a patient over a 0.035 inch outer diameter diagnostic guide wire. The infusion segment of the catheter will be positioned at the intended delivery site. The infusion segment is identified by radiopaque marker bands, and may be visualized under fluoroscopy by the clinician. The diagnostic guide wire will then be removed, while maintaining the position of the catheter. The Occluding Wire will be advanced through the catheter and hemostasis valve until the cap on the wire snaps into the hemostasis valve. The use of the occluding wire enhances controlled, localized dispersion of therapeutic solution through the infusion holes of the catheter.

Infusion of therapeutic solutions is made via the syringes, a hemostasis valve and a dual check valve or the squirt™ fluid delivery system. The therapeutic solution can be either infused by slow, continuous infusion or pulse infusion. Continuous infusion is the uninterrupted flow of infusion therapy over a period of time. Typically, the therapeutic solution is administered from an IV pump at a very low flow rate. Infusion by pulsing is the administration of small and quick injections of therapeutic solution delivered at repeated intervals. At the completion of the infusion therapy, the occluding wire and infusion catheter are removed.

Technology Comparison:

The Merit 4 French Fountain Infusion Catheter are technologically comparable to the predicate devices (Merit 5F Fountain) in construction and physical specifications. Also, design, manufacturing, and sterilization procedures are representative of current industry practices.

Test Summary, In-vitro:

Functional testing was performed on the Merit 4 French Fountain Infusion Catheter to evaluate the integrity and performance of the device. Based upon the results of this testing, Merit has determined that the device is safe and effective and is acceptable in design and construction for its intended use.

Test summary, In-vivo:

Clinical testing was not performed on the subject catheter due to the similarities to the predicate device.

Test Summary, Biocompatibility:

Biocompatibility testing was performed on the Merit 5 French Fountain Infusion Catheter in accordance with the requirements specified in International Standards Organization (ISO) 10993-1-1994 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests and the FDA General Program Memorandum No. G95-1. The Merit 5 French Fountain Infusion Catheter was found to be biocompatible, nontoxic and acceptable for its intended use. The Merit 4 French Fountain Infusion Catheters are manufactured from the same materials as the predicate device so they have also been found to be biocompatible, nontoxic and acceptable for their intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1999

Mr. Chester McCoy
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

Re: K992231
The FOUNTAIN™ Infusion Catheter and Occluding Guide Wire
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: June 25, 1999
Received: July 2, 1999

Dear Mr. McCoy:

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 legally marketed predicate 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.

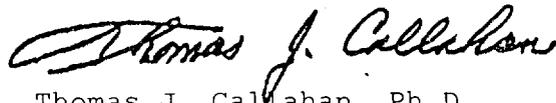
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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 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.

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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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

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

Attachment 2

Indications for Use Statement

510(k)
Number
(if Known)

K992231

Device Name

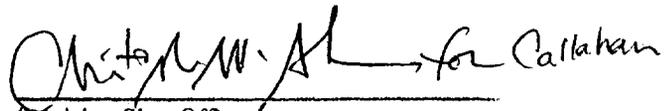
FOUNTAIN™ Infusion Catheter and Occluding Guide Wire

Indications for
Use

The FOUNTAIN™ Infusion Catheter and Occluding Guide Wire is intended to administer infusions of various therapeutic solutions into the peripheral vasculature of a patient

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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use

OR

Over-The-Counter Use