February 3, 2022

Merit Medical Systems, Inc.
Dennis Reigle
Regulatory Affairs Manager
1600 West Merit Pkwy.
South Jordan, Utah 84095

Re: K974067
Trade/Device Name: Fountain Infusion Catheter and Occluding Guide Wire
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Dennis Reigle:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 27, 1998. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2022.02.03 14:36:36 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Mr. Dennis (Dan) Reigle
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

Re: K974067
Fountain Infusion Catheter and Occluding Guide Wire
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: January 22, 1998
Received: January 23, 1998

Dear Mr. Reigle:

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 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.

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/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

INDICATIONS FOR USE STATEMENT

Merit Medical Systems, Inc.
510(k) Notification: K974067

Indications For Use:

The Fountain Infusion Catheter and Occluding Guide Wire will be used for the infusion of various therapeutic drugs 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)

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

(Optional Format 1-2-96)

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

510(k) Number ____

1 007

FEB 27 1998

K974067

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:

Dennis Reigle
Regulatory Affairs Manager
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095
(801) 253-1600
(801) 253-1684 fax

Contact Person:

Same as above

Date Summary Prepared: October 23, 1997

Device Name: Infusion Catheter and Occluding Guide Wire

Common Name: Infusion Catheter and Occluding/Guide Wire

Trade Name: Fountain™

Classification (if known): Intravascular Catheter

Predicate Devices:

Pulse Spray Catheter and Occluding Ball Wire K961763
AngioDynamics
(07/17/96)

Medwissen Infusion Catheter K904788
Medi-Tech
(12/17/90)

Multi-Sideport Catheter Infusion Set
Cook

MERIT MEDICAL
SYSTEMS, INC.
1600 WEST
MERIT PARKWAY
SOUTH JORDAN,
UTAH 84095
801-253-1600
FAX 801-253-1651

Device Description:

The Fountain™ Infusion Catheter has infusion holes at the distal end. The infusion holes are located at many locations around the catheter. The infusion segment of the catheter is indicated by two radiopaque marker bands.

The Occluding Guide Wire occludes the distal end of the Fountain Infusion Catheter. The proximal end of the occluding wire has a marker for verification of proper placement.

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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 Guide Wire will be advanced through the catheter until the ball on the wire "occludes" the distal tip of the infusion catheter. The use of the occluding wire enhances controlled, localized dispersion of therapeutic solution through the 0.0025 to 0.005" diameter infusion holes of the infusion catheter.

Infusion of therapeutic solutions is made via the syringes, a hemostasis valve and a dual check valve, all of which are included in the Merit Pulse Therapy Kit. The dual check valve allows for the uncomplicated loading of an infusate from a larger reservoir syringe source to a small 1 ml infusion delivery syringe. This permits subsequent injection without disconnecting from the delivery catheter. The fluid can be infused by continuous infusion, or pulse. Continuous infusion is the uninterrupted flow of infusion therapy over a period of time. Typically, the therapeutic solution is administered from an IV pump and at a very low flow rate. Infusion by pulsing is the administration of small and quick injections of therapeutic solution delivered at repeatable time intervals. The mechanical action from pulsing the therapeutic solution helps to break down clots. This mechanical action is also coupled with the enzymatic activity of the therapeutic solution to aid in breaking down the thrombus and restoring blood flow to the area. At the completion of the infusion therapy, the occluding wire and infusion catheter are removed.

Device Use: - continued

The description above references a Pulse Therapy Kit. The Fountain Infusion Catheter and Occluding Guide Wire will be marketed along with the Pulse Therapy Kit under the name "Fountain Infusion System". The instructions for use (IFU) is written for the Fountain Infusion System.

Device Characteristics:

Catalog Number	Description
IS5-45-10	5F, 45 cm Catheter, 10 cm Infusion length 0.035" O.D. Occluding Guide Wire 69 cm long
IS5-45-20	5F, 45 cm Catheter, 20 cm Infusion length 0.035" O.D. Occluding Guide Wire 69 cm long
IS5-90-5	5F, 90 cm Catheter, 5 cm Infusion length 0.035" O.D. Occluding Guide Wire 114 cm long
IS5-90-10	5F, 90 cm Catheter, 10 cm Infusion length .035" O.D. Occluding Guide Wire 114 cm long
IS5-90-20	5F, 90 cm Catheter, 20 cm Infusion length 0.035" O.D. Occluding Guide Wire 114 cm long
IS5-90-30	5F, 90 cm Catheter, 30 cm Infusion length 0.035" O.D. Occluding Guide Wire 114 cm long
IS5-135-5	5F, 135 cm Catheter, 5 cm Infusion length 0.035" O.D. Occluding Guide Wire 159 cm long
IS5-135-10	5F, 135 cm Catheter, 10 cm Infusion length 0.035" O.D. Occluding Guide Wire 159 cm long
IS5-135-20	5F, 135 cm Catheter, 20 cm Infusion length 0.035" O.D. Occluding Guide Wire 159 cm long
IS5-135-30	5F, 135 cm Catheter, 30 cm Infusion length 0.035" O.D. Occluding Guide Wire 159 cm long

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