K083576 (1/2)

SECTION 5: 510(k) SUMMARY

DEC 23 2008

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

CONTACT:
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DATE PREPARED:
December 1, 2008

TRADE OR PROPRIETARY NAME:
Miser Contrast Management System

CLASSIFICATION/ NAME:
Class II, Intravascular Administration Set (880.5440), Product Code FPA; General Hospital

PREDICATE DEVICES:
Miser Contrast Management System (K961794)

DEVICE DESCRIPTION:
Merit Miser Contrast Management System consists of the Contrast Spike Assembly and Contrast Burette Assembly.

During use, the spike assembly is inserted into a container of contrast media. The proximal tubing of the burette assembly is attached to the spike assembly and the longer, distal burette tubing segment is attached to a manifold port (not provided).

The burette is filled to the approximate 20mL level by first pinching the 2 wings of the vent valve mechanism together while squeezing the burette chamber, thus forcing air from the burette chamber. The wings are then released, closing the vent. The residual vacuum in the burette draws contrast media through the 2 backflow valves into the chamber until the vacuum is neutralized. The fluid level will remain at this level until the vent valve is opened or the contrast media is depleted.

The shut off (orange ball) valve located at the bottom of the burette chamber minimizes the potential for air to enter the system when the contrast media container is depleted. The filtered stopcock located below the burette chamber may be used to allow the contrast solution remaining in the tubing to be aspirated for injection into the patient.

INTENDED USE:
The Miser Contrast Management System is intended for the vascular administration of contrast media and saline.

Merit Medical Systems, Inc.	**Miser Contrast Management System** Special 510(k)	

TECHNOLOGICAL COMPARISON:
The modified device has the identical intended use and employs the same fundamental technology as the predicate device. The burette chamber material, burette venting mechanism, burette shutoff valve, and tubing formulation have been modified to address user preferences.

PERFORMANCE TESTING:
Verification and Validation Studies, conducted to demonstrate control of risks identified in Merit's Miser Clinical Risk Assessment, demonstrate that the modified devices met all of their pre-determined acceptance criteria and acceptably control the identified risks.

SUMMARY OF SUBSTANTIAL EQUIVALENCE:

Based on:

- Merit's conformance with Design Control requirements;
- Analyses of Risks associated with the Modified Device; and
- Results of Verification and Validation tests identified in the Clinical Risk Assessment demonstrating that predetermined acceptance criteria have been met and risks adequately controlled,

Merit concludes that the modified devices are as safe and effective as, and perform as well as, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Stephanie A. Erskine
Vice President, Corporate Regulatory Affairs
Merit Medical Systems, Incorporated
1600 West Merit Parkway
South Jordan, Utah 84095

DEC 23 2008

Re: K083576
Trade/Device Name: Miser Contrast Management System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 2, 2008
Received: December 3, 2008

Dear Ms. Erskine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K083576

Device Name:

Indications for Use:

The Miser Contrast Management System is intended for the vascular administration of contrast media and saline.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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