
Section 5
510(k) Summary for K100569

MAR 17 2011

General Provisions

Submitter Name: Merit Medical Systems, Inc.
Address: 1600 West Merit Parkway, South Jordan, UT 84095
Telephone Number: (801) 208-4187
Fax Number: (801) 253-6905
Contact Person: Lindsay Martin
Date of Preparation: February 26, 2010
Registration Number: 1721504

Subject Device

Trade Name: ASAP Catheter
Common/Usual Name: Merit ASAP Embolectomy Catheter
Classification Name: Catheter, Embolectomy

Predicate Device

Trade Name: Pronto V3 Extraction Catheter, Model 5003
Classification Name: Catheter, Embolectomy
Premarket Notification: K063371
Manufacturer: Vascular Solutions, Inc.

Classification

Class II per 21 CFR § 870.5150
Product Code: DXE
Review Branch: Division of Cardiovascular Devices

Intended Use

The intended use of the Merit Embolectomy Catheter is to remove or aspirate fresh, soft emboli and thrombi from vessels of the arterial system. Not for use in cerebral vasculature.

Device Description

The Merit Embolectomy Catheter is a dual lumen rapid exchange catheter, compatible with 0.014"/0.36 mm guide wires with related accessories. The catheter has a maximum outer diameter of 0.068"/1.73mm and a working length of 140 cm. The catheter has a radiopaque marker band located approximately 2 mm proximal to the distal tip. The catheter has three (3) non-radiopaque positioning marks located approximately 90cm, 100 cm, and 110 cm proximal of the distal tip.

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests was performed according to protocols based on the requirements of the following documents, and were shown to meet the

acceptance criteria that were determined to be applicable to the safety and efficacy of the device:

- ☑ ISO 10555-1, *Sterile, single-use intravascular catheters, Part 1. General requirements.*
- ☑ ISO 10555-2, *Sterile, single-use intravascular catheters, Part 2. Angiographic catheters*
- ☑ ISO 594-2, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*
- ☑ ISO 11135, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- ☑ ISO 10993-1, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing*, and the FDA Modified ISO 10993 Test Profile

☑The following is a list of all significant testing that was successfully completed:

Surface Condition

Force at Break

Freedom from Leakage 1 – Leak under Pressure

Freedom from Leakage 2- Aspiration Leak

Dimensional Verification

- Outside Diameter
- Effective Length
- Usable Length
- Depth Marks
- Tip Angle

Radio-detectability

Visual

Aspiration

Flow

Lubricious Coating Effectiveness – Coating Lubricity and Durability Test and Accelerated Aging Assessment

Coating Integrity- Dye Test

Lubricious Coating Length

Guide Wire Compatibility

Stiffness- Proximal, Mid, Distal Section

Kink Test- Proximal, Mid, Distal Section

Marker Band Retention

Rapid Exchange Lumen Attachment

Simulated Use Testing:

Tortuous Path- Tracking

Tortuous Path- Guide Wire

Tortuous Path- Crossing a deployed stent

Tortuous Path- Soft emboli aspiration

Biocompatibility Tests

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemocompatibility

Packaging performance before and after exposure to accelerated aging and simulated shipping and handling conditions

- bubble emission
- dye penetration
- seal peel tensile strength
- burst strength
- visual inspection

Summary of Substantial Equivalence

Based on the indications for use, design, and safety and performance test results, the subject Merit Embolectomy Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Pronto V3 Embolectomy Catheter manufactured by Vascular Solutions, Inc.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Merit Medical Systems, Inc.
c/o Ms. Lindsay Martin
1600 West Merit Parkway
South Jordan, UT 84095

Re: K100569

MAR 11 2011

Trade Name: Merit Embolectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: February 26, 2011
Received: March 1, 2011

Dear Ms. Martin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

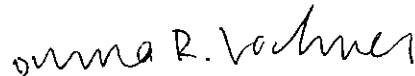
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100569

Device Name: Merit Embolectomy Catheter

Indications for Use:

The Merit Embolectomy Catheter is intended for use for the removal of fresh, soft emboli and thrombi from vessels of the arterial system.

Not for use in cerebral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Thomas R. Valiner
(Division Sign-Off)
Division of Cardiovascular Devices

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