K091584

Section 5

510(k) Summary

OCT 29 2009

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 208-4789
	Fax Number:	(801) 253-6919
	Contact Person:	Susan Christensen
	Date of Preparation:	May 28, 2009
	Registration Number:	1721504
Subject Device	Trade Name:	Merit MAK® (Mini Access Kit)
	Common/Usual Name:	Vessel Dilator/Introducer Sheath
	Classification Name:	Vessel Dilator for Percutaneous Catheterization
Predicate Device	Trade Name:	Merit® MAK (Mini Access Kit)
	Classification Name:	Vessel Dilator for Percutaneous Catheterization
	Premarket Notification:	K031691
	Manufacturer:	Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1310, 74 DRE Division of Cardiovascular Devices	
Intended Use	The Merit MAK (Mini Access Kit) is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.	

	The Merit MAK® (Mini Access Kit) utilizes a small diameter coaxial introducer/dilator pair and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred.
Device Description	The Merit MAK® consists of the following components: One (1) 4F or 5F Coaxial Introducer/Dilator Pair One (1) 21 gauge Introducer Needle One (1) 0.018" (0.46mm) Guide Wire Two new versions of guide wires will be offered: Stainless Steel Wire with Palladium Tip Nitinol Wire with Palladium Tip
Technological Characteristics	Technological characteristics of the subject Merit MAK® with palladium tip guide wire are substantially equivalent to those of the predicate, the currently marketed Merit MAK with platinum tip guide wire [K031691].
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 industry standards and guidances and were shown to meet the acceptance criteria that were determined to demonstrate the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject Merit MAK® with palladium tip guide wire meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the currently marketed Merit MAK with platinum tip guide wire manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Merit Medical Systems, Inc.
c/o Ms. Susan Christensen
Regulatory Affairs Specialist II
1600 West Merit Parkway
South Jordan, UT 84095

OCT 29 2009

Re: K091584
Trade/Device Name: Merit MAK® (Mini Access Kit)
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II (two)
Product Code: DRE
Dated: September 30, 2009
Received: October 1, 2009

Dear Ms. Christensen:

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 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K091584

Device Name: Merit MAK® (Mini Access Kit) with Palladium Tip Guide Wire

Indications for Use:

The Merit MAK® (Mini Access Kit) is intended for percutaneous placement of a 0.035" (0.89mm) or 0.038" (0.97mm) guide wire into the vascular system.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091584