Section 5

510(k) Summary

APR 13 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:	January 19, 2009
	Registration Number:	1721504
Subject Device	Trade Name:	55cm ProGuide™
	Common/Usual Name:	Chronic Dialysis Catheter
	Classification Name:	Implanted Hemodialysis Catheter
Predicate Devices	Trade Name:	ProGuide Chronic Dialysis Catheter
	Classification Name:	Implanted Hemodialysis Catheter
	Premarket Notification:	K042016
	Manufacturer:	Merit Medical Systems, Inc.
	Trade Name:	EvenMore® Chronic Hemodialysis Catheter
	Classification Name:	Implanted Hemodialysis Catheter
	Premarket Notification:	K040402
	Manufacturer:	AngioDynamics® Inc.
Classification	Class III 21 CFR § 876.5540, 78 MSD Division of Gastroenterology and Renal Devices	
Intended Use	The ProGuide Chronic Dialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be implanted percutaneously and is primarily placed in the internal jugular or subclavian vein of an adult patient. Catheters greater than 40 cm are intended for femoral vein insertion.	

Device Description	The 55cm ProGuide Chronic Dialysis catheter is a 14.5 French dual lumen catheter that provides two dedicated (arterial/venous) lumens. The arterial and venous lumen extension legs have female connectors and atraumatic occlusion clamps which close the access to the lumen. The catheter comes with a stiffening stylet to help facilitate catheter insertion over-the-wire placement.
Technological Characteristics	Technological characteristics of the subject 55cm ProGuide Chronic Dialysis Catheter are equivalent to those of the predicates, the currently marketed ProGuide Chronic Dialysis catheter [K042016] and the AngioDynamics' EvenMore® Chronic Hemodialysis Catheter [K040402]. This equivalence extends to the device's design, materials, and function with the predicate the currently marketed ProGuide Chronic Dialysis catheter [K042016]. The useable length specifications and anatomical placement locations are equivalent with the AngioDynamics' EvenMore® Chronic Hemodialysis Catheter [K040402].
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 be applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject 55cm ProGuide Chronic Dialysis Catheter meets the minimum requirements that are considered essential for its intended use and is substantially equivalent to the predicate devices, the currently marketed ProGuide Chronic Dialysis catheter manufactured by Merit Medical Systems, Inc. and the EvenMore Chronic Hemodialysis Catheter, manufactured by AngioDynamics, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan Christensen
Regulatory Affairs Specialist II
Merit Medical Systems, Inc.
1600 West Merit Parkway
SOUTH JORDAN UT 84095

APR 13 2009

Re: K090148
Trade/Device Name: 55 cm ProGuide Dialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 19, 2009
Received: January 21, 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 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

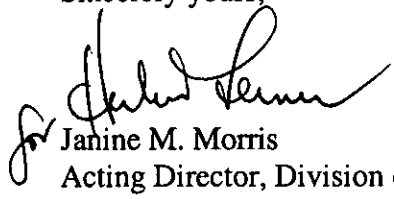
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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.dsma/dsmamain.html.

Sincerely yours,



for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K090148

Section 4

Indications for Use Statement

510(k) Number (if known): K090148

Device Name: 55cm ProGuide Chronic Dialysis Catheter

Indications for Use:

The ProGuide Chronic Dialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis.

It may be implanted percutaneously and is primarily placed in the internal jugular or subclavian vein of an adult patient.

Catheters greater than 40 cm are intended for femoral vein insertion.

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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K090148