APR 25 2006

510(k) Summary

Submitted by: KENSEY NASH CORPORATION
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Jennifer J. Bosley, MBA, RAC
Regulatory Affairs Specialist
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Date Prepared: March 6, 2006

510(k) #: **K060016**
Device Trade Name: ThromCat™ Thrombectomy Catheter System
Common/Usual Name: Thrombectomy Device
Proposed Classification: Catheter, Peripheral, Atherectomy
21 CFR 870.4875, MCW, Class II

Device Description:
ThromCat Thrombectomy Catheter System is a single-use, disposable device that performs percutaneous maceration and removal of thrombus and restoration of blood flow. The device consists of a 5.5 Fr x 4.5 Fr infusion/extraction catheter, a DC-powered infusion/extraction pump, and an extraction line and bag. The stainless steel helix is enclosed within a radiopaque, atraumatic flexible tip and shaft, preventing direct contact with the vessel wall. The integrated pumps, tubing and 150 cm length catheter provide an infusion flow to "wash" the vessel, while simultaneously providing an extraction flow to remove thrombus.

Intended Use:
ThromCat™ Thrombectomy Catheter System is indicated for mechanical removal of thrombus from synthetic hemodialysis access grafts and native vessel dialysis fistulae.

Predicate Devices:

Manufacturer	Device	510(k) #
ev3 Inc.	X-Sizer® Catheter System	K021096
Microvena Corporation	Amplatz Thrombectomy Device	K982657

Substantial Equivalence:
ThromCat is similar with regard to materials, intended use, principles of operation and technological characteristics to the predicate mechanical thrombectomy devices in terms of section 510(k) substantial equivalence; any differences that may exist do not significantly affect the safety and efficacy of the device. Results of bench testing and animal studies demonstrate ThromCat is as safe and effective as the legally marketed predicate devices.

Non-Clinical Testing:
ThromCat has undergone non-clinical testing, e.g., biocompatibility, EMC, electrical safety, mechanical testing and animal studies that provide reasonable assurance of safety and effectiveness for its intended use. *In vitro* and *in vivo* comparison testing was conducted on ThromCat and the predicate device, X-Sizer Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2006

Kensey Nash Corporation
c/o Ms. Jennifer Bosley
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, PA 19341

Re: K060016
Trade Name: ThromCat™ Thrombectomy Catheter System
Regulation Number: 21 CFR 870.4875
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MCW
Dated: April 6, 2006
Received: April 7, 2006

Dear Ms. Bosley:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 Statement

510(k) Number (if known): K060016

Device Name: ThromCat™ Thrombectomy Catheter System

Indications For Use:

ThromCat™ Thrombectomy Catheter System is indicated for mechanical removal of thrombus in synthetic hemodialysis access grafts and native vessel dialysis fistulae.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Per 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 K060016