

MAY 4 2000

**Baxter**

### 510(k) Summary

**Submitter:** Baxter Healthcare Corporation, CardioVascular Group

**Contact Person:** Diane Peterson, Senior Regulatory Affairs Associate

**Date Prepared:** November 9, 1999

**Trade Name:** Baxter Percutaneous Mechanical Thrombectomy (PMT) Device

**Classification Name:** Peripheral Atherectomy Catheter

**Predicate Devices:** MICROVENA Amplatz Thrombectomy Device (ATD)

**Device Description:** The Baxter Percutaneous Mechanical Thrombectomy (PMT) Device consists of a 6-French catheter terminating at a stainless steel housing in which a small diameter helical screw is attached to a drive shaft. A battery-operated motor rotates a flexible drive shaft connected to the helical screw at approximately 3,100 rpm. A central lumen within the device is provided for guidewire placement or infusion of fluids.

**Intended Use:** The Baxter Percutaneous Mechanical Thrombectomy (PMT) Device is designed for percutaneous removal of thrombus using aspiration and an internal helical screw to fragment and remove thrombus. The Baxter PMT device is indicated for removal of thrombus in synthetic dialysis access grafts.

**Comparative Analysis** It has been demonstrated (through clinical studies) that the Baxter Percutaneous Mechanical Thrombectomy (PMT) Device is as safe and effective as the predicate device for the removal of thrombus within synthetic dialysis access grafts.

**Functional/Safety Testing:** The Baxter Percutaneous Mechanical Thrombectomy (PMT) Device has successfully undergone design validation, as well as functional, animal and clinical testing.

**Conclusion:** The Baxter Percutaneous Mechanical Thrombectomy (PMT) Device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 4 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Diane Peterson  
Senior Regulatory Affairs Associate  
Baxter Healthcare Corporation  
Cardio Vascular Group  
17221 Red Hill Avenue (Irvine)  
P.O. Box 11150  
Santa Ana, CA 92711-1150

Re: K993816  
Baxter Percutaneous Mechanical Thrombectomy Device  
Regulatory Class: II (two)  
Product Code: 74 MCW  
Dated: February 22, 2000  
Received: February 23, 2000

Dear Ms. Peterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

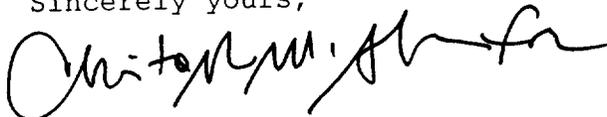
Page 2 - Ms. Diane Peterson

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K993816

Device Name: Baxter Percutaneous Mechanical Thrombectomy (PMT) Device

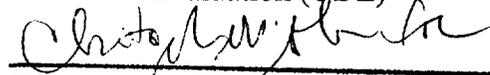
Indications for Use:

Baxter Percutaneous Mechanical Thrombectomy (PMT) Device is indicated for removal of thrombus in synthetic dialysis access grafts.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office Of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K993816

Prescription Use  \_\_\_\_\_

OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)