K052844

MAR 2 0 2006

Richter & Rothe AG
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Date: October 3, 2005

Department of Health and Human Services
Center of Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section

510(K) SUMMARY

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	Richter & Rothe AG
Registration #	3005186310
Address:	Wilhelm Leuschner Platz 12 04107 Leipzig Germany
Contact Person:	Joachim Richter CEO
Phone:	+49-341-2254-1220
Fax:	+49-341-2254-1222

b. Device Name:

Trade/Proprietary Name:	KAVS Catheter
Common/Usual Name:	Intravascular Catheter
Classification Name:	Cardiovascular, intravascular occluding, temporary
Device:	21 CFR 870.4450, Product Code: MJN

c. Legally Marketed Predicate Device(s)

Our device is substantially equivalent to the legally marketed predicate devices cited in the table below:

Manufacturer	Device	510(k) #
VeinRx	InfusionCath	K041517
Cook Inc.	LDOB Occlusion Balloon Catheter	K002286

d. Description

The KAVS catheter is an intravascular catheter that is introduced into the patient's vein for short-term therapeutic use. The catheter has a balloon at the distal end, that when expanded, will temporarily block the blood flow in that segment of the vein. This allows the physician to inject medication through the central lumen of the catheter for patient treatment. Once the treatment is complete the physician can then remove the medication, prior to removing the catheter.

Procedure: The catheter is advanced through a phlebotomy (incision in the vein under observation) or through an introducer sheath under ultrasound control, into the vein. The ultrasound control and radio-opaque catheter allow the physician to guide the catheter until the tip is positioned at the vascular area of interest. Once this position is verified, under ultrasound, the balloon is filled with a sterile saline solution (0.9%), until the blood flow is blocked. The maximum filling volume of the balloon, as identified in the

user guide, should not be exceeded in order to prevent possible balloon perforations. The prescribed medication is then administered through the central lumen and will enter the vein through small holes in the tip of the catheter. Once the medication has had adequate contact time, the medication can then be aspirated and removed from the patient. The balloon is then emptied, through the separate balloon lumen, and the catheter is removed from the patient.

The KAVS Catheter prevents the prescribed medication from being washed away by normal blood flow. This results in a controlled contact time of the medication with the venous wall for an improved therapeutic use.

The KAVS catheter is a double-lumen catheter made of radio-opaque polyurethane, which is equipped with a latex balloon at the distal end. At the proximal end of the coaxial catheter there is a double attachment, consisting of a Luer-lock adapter for access to the main catheter lumen, for injection of prescribed medication, and a laterally mounted Luer-lock adapter with a stopcock for filling the balloon. The rounded catheter tip is closed, underneath the balloon there are three openings, which serve as outlet openings for the main catheter lumen.

e. Intended use

The KAVS Catheter is intended to temporarily inhibit blood flow in isolated sections of peripheral veins in order to inject physician prescribed medications.

f. Summary of technological considerations

The KAVS Catheter is substantially equivalent to the predicate devices. Both catheters are designed to block the blood flow in order to inject a prescribed medication for therapeutic use. The KAVS Catheter is as safe, as effective, and performs as well as or better than the predicate device. 807.92(b)(3).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2006

Richter & Rothe AG
c/o Mr. Joachim Richter
Wilhelm Leuschner Platz 12
D04107 Leipzig
GERMANY

Re: K052844
KAVS Catheter, Models 1107100 and 1107060
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: II (two)
Product Code: MJN
Dated: March 13, 2006
Received: March 14, 2006

Dear Mr. Richter:

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

510(k) Number (if known): K052844

Device Name: KAVS Catheter

Indications for Use:

The KAVS Catheter is intended to temporarily inhibit blood flow in isolated sections of peripheral veins in order to inject physician prescribed medications.

Prescription Use __X__ AND/OR Over the Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lichtner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052844