

MAR 20 2006

K 052844



**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).



MAR 20 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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.

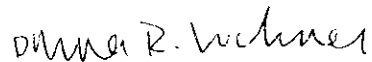
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Page 2 – Mr. Joachim Richter

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  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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana P. Kochner*  
(Division Sign-Off)  
Division of ~~Controlled~~ Devices

510(k) Number K052844