

AUG - 5 2004

510(k) SummaryGeneral Information

Classification	Class II
Trade Name	InfusionCath
Submitter	VeinRx, Inc. 8210 NW 27 th Street Miami, FL 33122 Tel: (305) 716-7000
Contact	Scott Jahrmarkt President & CEO

Intended Use

The InfusionCath is intended for the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Devices

K013635	Trellis Infusion System Bacchus Vascular, Inc.
K992940	LeMaitre Balloon Catheter with Irrigation Vascutech, Inc.
K913517	Isolate Infusion Catheter Lake Region, Inc.

Device Description

The VeinRx InfusionCath is used to temporarily occlude a vessel in the peripheral vasculature and then deliver a predetermined dose of a physician specified fluid proximally along the inner lumen of the vessel. The VeinRx InfusionCath is comprised of a distal occlusion balloon, a

variable treatment length catheter body with elution holes, and a proximal trifurcated Luer connection hub. The Trifurcated hub allows connections for to the following three main systems of the device. The Luer Lock connections for balloon inflation, infusion valve operation and fluid infusion. The device is provided sterile and for single patient use.

Materials

All materials used in the manufacture of the InfusionCath are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included mechanical strength testing, bond strength, balloon inflation / deflation and fluid infusion.

In vivo animal testing comparing the InfusionCath to a commercially available predicate product was conducted. The products were used per their respective Instructions for Use. The results showed the InfusionCath was equivalent to the predicate device.

Summary of Substantial Equivalence

The InfusionCath is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2004

VeinRx, Inc.
c/o Mr. Scott Jahrmarkt
President & CEO
8210 NW 27th Street
Miami, FL 33122

Re: K041517
InfusionCath
Regulation Number: 21 CFR 870.1210
Regulation Name: Infusion Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: June 7, 2004
Received: June 9, 2004

Dear Mr. Jahrmarkt:

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.

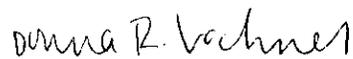
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Page 2 – Mr. Scott Jahrmarkt

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 (301) 594-4648. 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/dsma/dsmamain.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):

This application K041517

Device Name:

InfusionCath

Indications For Use:

The InfusionCath is intended for the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Danna P. Cochran
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041517