

510(k) Summary

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Device Name

Trade Name: Vector⁴™
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter
Classification: II
Product Code: LIT

Predicate Device

The device is substantially equivalent to the r4 Vascular Vector⁴™ PTA Balloon Dilatation Catheter (K121385).

Indications for Use/Intended Use

The Vector⁴™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arterio-venous dialysis fistulae.

The Vector Catheter is not indicated for use in the coronary arteries or for placement of or post dilatation of stents.

Device Description

The Vector⁴™ PTA Balloon Catheter is a high pressure, non-compliant balloon catheter with a radio-opaque coating on the balloon. The radio-opaque coating on the working length of

the balloon minimizes or eliminates the need for using contrast solution to inflate the balloon. The radio-opaque coating delineates the working length of the balloon and provides continuous fluoroscopic visibility during balloon placement. Saline may be used to inflate the balloon without affecting visualization. Contrast mixture may be used at the discretion of the physician.

Technological Characteristics

The Vector⁴™ PTA Balloon Dilatation Catheter was cleared under K121385. The fundamental scientific technology and materials for the Vector⁴™ PTA Balloon Catheter remain the same.

It is a coaxial dual lumen over-the-wire balloon dilatation catheter. The central lumen accommodates guide wires up to 0.035 inches in diameter while the outer lumen is the inflation lumen for the balloon. The catheter includes an atraumatic tip to ease advancement of the catheter to and through the stenosis. The distal tip is visible under fluoroscopy.

The balloon is a high pressure composite balloon with a radio-opaque coating on the working length to help visualize placement within the lesion during both placement and inflation without the use of contrast. The balloon's rated burst pressure is 30 atm.

The catheter is supplied sterile and non-pyrogenic. Different balloon sizes (5 mm to 10 mm) and catheter lengths (50 to 135 cm) are available. The proximal end of the catheter contains a hub with two female luer locks.

The device is compatible with 6-7F introducers. The introducer compatibility for each device size is listed on the device label itself. The materials used in the construction are biocompatible and latex free.

The modifications to the Vector⁴™ PTA Balloon Dilatation Catheter are as follows.

- 1) The balloon will be coated with Parylene C coating, referred to throughout as Parylene, providing a natural lubricity for insertion and withdrawal through the introducer.
- 2) Each balloon catheter hub will be laser marked to include the balloon and introducer size, rated burst pressure and the product name, Vector⁴™ PTA Balloon Catheter for customer convenience.
- 3) The balloon protector ID for the 5x40mm balloon was increased slightly.

There are no changes in the balloon catheter dimensions or significant changes in weight with these modifications.

Performance Data

Based on the risk analysis of the modified device, and testing was conducted on the modified Vector⁴™ PTA Balloon Dilatation Catheter. The testing performed on the modified devices was:

Vector⁴™ PTA Balloon Dilatation Catheter

- Balloon rated burst pressure
- Balloon compliance
- Balloon Diameter Sizing
- Inflation/deflation times
- Repeat inflation
- Removal, Refold and Reuse
- Crossing Profile
- Coating integrity/Particulates
- Balloon Protector
- Guide Wire and Introducer Compatibility
- Balloon Burst
- Aged Balloon Testing: Rated Burst Pressure, Balloon Compliance, Balloon Diameter Sizing, Inflation/deflation times, Repeat Inflation, Removal/Refold & Reuse, Flexibility/ Kink, Crossing Profile, Particulate/Coating Integrity, Balloon Protector, Guide Wire/Introducer Compatibility and Balloon Burst

All devices met the performance specifications.

The device is sterilized by ethylene oxide to an SAL 10^{-6} level and the device is biocompatible meeting the requirements of ISO 10993-1.

After accelerated aging of the device, a sub-set of the above listed tests that may be affected by aging were repeated.

The bench testing demonstrated that the device meets specifications before and after aging, indicating that the device is as safe and effective as the predicate device.

Substantial Equivalence

The modified Vector^{4™} PTA Balloon Catheter is substantially equivalent to the Vector^{4™} PTA catheter (K121385). They have the identical intended use, and treat the same target population. Both devices are intended to treat peripheral arteries. The manner in accessing and treating lesions in all these arteries is identical.

The devices are identical in design with the exception of the addition of Parylene coating, the laser marked hub and a slight increase in the ID of the balloon protector.

Conclusion

The modified Vector^{4™} PTA Balloon Catheters and the predicate Vector^{4™} PTA Balloon Catheters have identical intended use and similar technological characteristics and are therefore substantially equivalent. The bench testing of the Vector^{4™} PTA Balloon Dilatation Catheters met all the product specifications. These tests demonstrate that the Vector^{4™} PTA Balloon Dilatation Catheters are as safe and effective as the predicate device.



June 6, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

r4 Vascular, Inc.
c/o Ms. Laurie Lewandowski, Consultant
Honkanen Consulting, Inc.
738 Saddle Wood Drive
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Re: K131329

Trade/Device Name: Vector ⁴™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LFT
Dated: May 7, 2013
Received: May 8, 2013

Dear Ms. Lewandowski:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
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Enclosure
