DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

July 19, 2017

Curatia Medical Co.
% Mr. Bill Jacqmein
Regulatory Affairs Consultant
JCQ Consulting
11218 Zest Court
Blaine, MN 55449

Re: K171290
Trade/Device Name: Vela RX PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 28, 2017
Received: May 2, 2017

Dear Mr. Jacqmein:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171290

Device Name

Vela RX PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*

The Vela RX PTA Balloon Dilatation Catheter is intended for use in percutaneous transluminal angioplasty (PTA) of the femoral, popliteal, infra popliteal and renal arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

A 510(k) summary in accordance with the requirements of 21 CFR 807.92.

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Date Prepared: March 2017

Proprietary Name: Vela RX PTA Balloon Dilatation Catheter

Common Name: Percutaneous catheter

Product Code: LIT – Catheter, Angioplasty, Peripheral, Transluminal

Device Classification: Class II, 21 CFR 870.1250 – Percutaneous Catheter

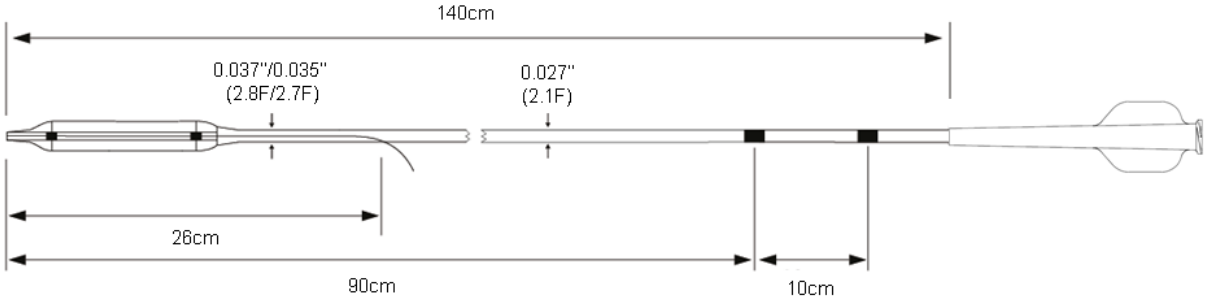
Predicate Devices: Ultraverse RX PTA Balloon Dilatation Catheter (K131199)

Reference Device: Navajo PTA Catheter (K141354)

Device Description:

The Vela RX PTA Balloon Dilatation Catheter has a 0.014'' (0.36mm) rapid exchange co-axial design, which consists of proximal tube with hub and strain relief, transition tube, and distal tube with a balloon at the distal tip. The balloon is made of a Pebax low-compliant material and will expand to a known diameter and length at 6 atmospheres pressure. Two radiopaque markers under the balloon aid in positioning the balloon working length under the fluoroscopy. The nominal inflated balloon diameters range from 1.5mm to 4.0mm with balloon working lengths of 10mm to 40mm. The effective catheter length is 140cm, and is provided with a hydrophilic coating on the distal catheter shaft. The maximum compatible guide wire to be used with the Vela RX PTA Balloon Dilatation Catheter is 0.014'' (0.36mm), and the compatible introducer sheath size is 4F.

Figure 1: Detailed Device Description



Indications for Use:

The Vela RX PTA Balloon Dilatation Catheter is intended for use in percutaneous transluminal angioplasty (PTA) of the femoral, popliteal, infra popliteal and renal arteries.

Comparison to Predicate Devices:

Vela RX PTA Balloon Dilatation Catheter is functionally equivalent to the following predicate device: Ultraverse RX PTA Balloon Dilatation Catheter (Bard Peripheral Vascular, K131199 cleared May 30, 2013).

The following table demonstrates the functional specifications of Vela RX PTA Balloon Dilatation Catheter are substantially equivalent to the predicate devices.

Table 1: Functional Specification Comparison

Functional Specification	***Vela RX PTA Balloon Dilatation Catheter***	***Ultraverse RX PTA Dilation Catheter***	***Comparison Result***
Balloon and Catheter Materials	Nylon/Pebax	Nylon/Pebax	Same
Catheter Design	Distal OTW w. RX wire exchange, Proximal hypotube	Distal OTW w. RX wire exchange, Proximal hypotube	Same
Min. Sheath Size	4F	4-5F	Same
Max. Guide Wire Size	0.014″	0.014″	Same
Catheter Length	140cm	80, 150, 200 cm	Within range
Balloon OD	1.5-4.0mm	1.25, 1.5-4.0mm	Within range
Balloon Length	10,20,30,40mm	15,20,40,60, 120,200,250mm	5mm shorter than the predicate device. But within other similar products' spec. (See table below) Additionally, shorter balloons sizes are less risk because they do not cover/dilate as much healthy tissue as a larger balloon size would.
Balloon Marker	Dual Pt/Ir Markers	Dual Pt/Ir Markers	Same
Nominal Pressure	6atm	6atm	Same
Balloon RBP	16atm for 3.5-4.0mm balloons; 18atm for 2.5-3.0mm balloons 20atm for 1.5-2.0mm	15-16atm	RBP of 2 atm higher than its predicate devices in some balloon sizes, but within other similar products' spec. (See table below)

Indication for Use	For use in percutaneous transluminal angiogplasty (PTA) of the femoral, popliteal, infra popliteal and renal arteries.	For use in Percutaneous Transluminal Angioplasty of the renal, femoral, popliteal, infra-popliteal, tibial, and peroneal arteries. This catheter is not for use in coronary arteries.	Similar

In addition to the Ultraverse, the Curatia Navajo PTA catheter is also provided as a reference. Please see the comparison table below.

Functional Specification	***Vela RX（CML）***	***Navajo PTA（CML）***
FDA registration No.	K171290	***K141354***
Min. Sheath Size	4F	5F
Max. Guide Wire Size	0.014''	0.035''
Catheter Length	140 cm	80 to 130 cm
Balloon OD	1.5-4.0 mm	5 to 10 mm
Balloon Length	10,20,30,40 mm	40 to 80 mm
Nominal Pressure	6 atm	6 to 8 atm
Balloon RBP	20atm：1.5-2.0mm 18 atm: 2.5-3.0 mm 16 atm: 3.5-4.0 mm	14 to 16 atm
Indication for Use	For use in percutaneous transluminal angiogplasty (PTA) of the femoral, popliteal, infra popliteal and renal arteries.	The catheter is intended to dilate stenoses in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries); and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Comparison of Indications for Use to Predicate Devices:

Based on the above comparison, the indications for use of the Vela RX PTA Balloon Dilatation Catheter is similar to that of the Ultraverse. Therefore, the Vela RX PTA Balloon Dilatation Catheter can be considered substantially equivalent to its predicate device.

Comparison of Technological Characteristics to Predicate Devices:

Based on the above comparison, the design, construction, and performance characteristics of the Vela RX PTA Balloon Dilatation Catheter is similar to that of Ultraverse. Therefore, the Vela RX PTA Balloon Dilatation Catheter can be considered substantially equivalent to its predicate devices.

Summary of Performance Data and Substantial Equivalence:

The Vela RX PTA Balloon Dilatation Catheters were designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre-defined acceptance criteria. The Vela RX PTA Balloon Dilatation Catheters have been tested and shown to be compliant with the following standards documents:

- ISO 10555-1:2013- Intravascular catheters – Sterile, single-use intravascular catheters – Part 1: General requirements
- ISO 10555-4:2013- Intravascular catheters – Sterile, single-use intravascular catheters – Part 4: Balloon dilatation catheter
- ISO 10993-1:2009- Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-3:2014- Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2002+AMD1:2006-Biological testing of medical and dental materials and devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009- Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006- Biological testing of medical and dental materials and devices – Part 11: Tests for systemic toxicity
- ISO 10993-12:2012- Biological testing of medical and dental materials and devices – Part 12: Sample Preparation And Reference Materials
- ISO 11135: 2014 Sterilization of health-care products-Etylene oxide–Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11607-1: 2009(R2014)- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

Performance Testing:

To demonstrate substantial equivalence of Vela RX PTA Balloon Dilatation Catheter to the predicate devices, the technological characteristics and performance criteria were evaluated using the bench testing recommendations outlined in the FDA Guidance Document "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" dated September 8, 2010. The following performance tests were completed:

Dimension
Catheter Preparation, In/deflation Time
Catheter Flexibility and Kink
Torque Strength
Balloon Fatigue（w/ & w/o stent）
Balloon Compliance
Balloon Rated Rupture Pressure（w/ & w/o stent）
Catheter Shaft Pressure Integrity
GW Lumen Collapse Pressure
Catheter Bond Tensile Strength
Catheter Shaft Coating Integrity
Radiopacity

The results of these tests demonstrate the technological characteristics and performance criteria of the Vela RX PTA Balloon Dilatation Catheter are adequate for its intended use, and is substantially equivalent to the predicate devices.

Biocompatibility:

To demonstrate the biological safety of the body-contacting materials and substantial equivalence of the Vela RX PTA Balloon Dilatation Catheter to its predicate devices, the following biocompatibility testing was performed in accordance with ISO 10993 and the FDA Guidance Document "Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"" dated June, 2016:

Cytotoxicity
Sensitization
Irritation (Intracutaneous Reactivity)
Systemic Toxicity (acute)
Pyrogenicity
Hemocompatibility (Hemolysis, Thrombogenicity, and Immunology)
Genotoxicity (Bacterial Reverse Mutation Assay, Mouse Lymphoma Mutagenesis Assay)

The results from these tests demonstrate that Vela RX PTA Balloon Dilatation Catheter is biocompatible for its intended use.

Conclusion:

Based on comparison of indications for use, technological characteristics, safety and performance testing, biocompatibility testing, the Vela RX PTA Balloon Dilatation Catheter has been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate devices.