DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 25,2016

VentureMed Group
Ms. Tiffini Diage, MPH
Regulatory Affairs Consultant
5855 Monroe St, Suite 220 A
Sylvania, OH 43560

Re: K152789
Trade/Device Name: Flex Scoring Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: April 21, 2016
Received: April 25, 2016

Dear Ms. Diage,

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 yours,

Kenneth J. Cavanaugh -S

for

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 on last page.*

510(k) Number *(if known)*
K152789

Device Name
FLEX Scoring Catheter

Indications for Use *(Describe)*
The FLEX Scoring Catheter is indicated for use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

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|---|---|
| **Submitter:** | VentureMed Group, Ltd<br>5855 Monroe St, Suite 200<br>Sylvania, OH 43560 |
| **Contact Person:** | Tiffini Diage<br>Regulatory Affairs Consultant<br>Phone: 707.799.6732<br>E-mail: tdiage@raechelon.com |
| **Date Prepared:** | 5/17/2016 |
| **Trade Name:** | FLEX™ Scoring Catheter |
| **Common Name:** | Percutaneous Catheter |
| **Classification:** | Class II |
| **Product Code:** | PNO - 21 CFR 870.1250 |
| **Predicate Device(s):** | The subject device is equivalent to the following devices:<br>• K113103 – SplitWire Percutaneous Transluminal Angioplasty Scoring Device |
| **Device Description:** | The FLEX™ Scoring Catheter is a sterile, single use, disposable device designed to facilitate the dilation of stenoses. The device has a working length of 120cm and is comprised of three scoring elements at the distal end. The distal end also contains an atraumatic tip and radiopaque maker band to aid in proper placement of the catheter. When the device is unsheathed the scoring elements are expanded to contact the plaque. The device scores the plaque as it is retracted. Once the desired plaque is scored the device is exchanged for a PTA balloon.<br><br>The device is compatible with0.18" guidewires. |
| **Technical Comparison Table** | |

| | FLEX™ Scoring Catheter (Subject Device) | SplitWire Percutaneous Transluminal Angioplasty Scoring Device (Predicate Device) |
|---|---|---|
| **510(k) Number Decision Date** | K152789 | K113103 |
| **Manufacturer** | VentureMed Group Ltd | Rex Medical |
| **Classification** | Class II | Class II |
| **Regulation** | 21 CFR 870.1250 | 21 CFR 870.1250 |
| **Indications for Use** | indicated for use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. | indicated for use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. |
| **Intended Use** | Same | To facilitate the dilation of stenotic vessels |
| **Overall Device Length** | 120cm | 90cm, 180cm, 260cm |
| **Balloon Compatibility** | Not applicable – device not in vessel at same time as balloon | 20 – 80mm |
| **Integrated Balloon** | No | No |
| **Visibility** | Radiopaque markerband at distal tip | Radiopaque coil at distal tip, plus 2 markerbands for balloon placement |
| **Expansion Mechanism** | Operator expanded | Balloon expanded |
| **Scoring Member** | 3 | 1 |
| **Scoring Member Height** | 0.010” | 0.014” |
| **Scoring Member Expanded Size** | 5 mm | Dependent on inflated balloon diameter |
| **Scoring Member Depth Control** | Yes | No |
| **Deflection** | Yes < 1ATM | Yes 3ATM |
| **Scoring Member Fixed to Balloon** | No | No |
| **Sterilization** | Same | Ethylene Oxide |
| **Single Use Only** | Same | Yes |

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| **Functional and Safety Testing to Determine Substantial Equivalence:** | To verify that the device design meets its functional and performance requirements, representative samples of the device underwent bench testing. Testing included:<br>• General Requirements for Intravascular Catheters - ISO 10555-1<br>• Biocompatibility Testing - ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process<br>• Sterilization Validation Testing - ISO-11135-1 Sterilization of Health Care Products. Ethylene Oxide Sterilization Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices<br>• Simulated Use Testing<br>*In Vivo* GLP animal testing, cadaveric studies, and clinical evaluations were also performed and demonstrated the FLEX device meets user needs and intended use. |
| **Conclusion:** | VentureMed Group considers the FLEX™ Scoring Catheter to be substantially equivalent to the predicate device listed above. The subject device has the same intended use, principles of operation, and similar design features. Bench testing and pre-clinical animal studies demonstrate that none of the technical differences raise any new questions of safety and effectiveness. |