September 11, 2020

VentureMed Group, Inc.
Ms. Jill Schweiger
Vice President of Clinical, Regulatory, and Quality Assurance
2800 Campus Drive, Suite 50
Plymouth, Minnesota 55441

Re: K202187

Trade/Device Name: FLEX Vessel Prep System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: PNO
Dated: August 3, 2020
Received: August 4, 2020

Dear Ms. Schweiger:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for
devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see
https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-
combination-products); good manufacturing practice requirements as set forth in the quality systems (QS)
regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for
combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-
542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-
mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including
information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn
(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the
Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See
the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE
by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Device Name
FLEX Vessel Prep™ System

Indications for Use
The FLEX Vessel Prep™ System 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. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.
**510(K) SUMMARY**

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

**ADMINISTRATIVE INFORMATION**

510(k) Owner's name, address, phone, and fax numbers:

VentureMed Group, Inc.
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Fax: 419-558-4171

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Secondary Submission Contact: Sara Petrie
Director of Quality Assurance and Regulatory
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Email: spetrie@venturemedgroup.com

Date Summary Prepared: 31 August 2020

Trade Name: FLEX Vessel Prep™ System

Common Name: Percutaneous Catheter

Classification Name: Catheter, Percutaneous, Cutting/Scoring

Classification Regulation: 21 CFR 870.1250

Class: II

Panel: Cardiovascular

Classification Product Code: PNO
**PREDICATE DEVICE**

The subject device is equivalent to the following device:
K152789 – FLEX Vessel Prep™ System

**REFERENCE DEVICE**

K182713 – Scoreflex PTA Scoring Balloon Catheter.

**DEVICE DESCRIPTION**

The FLEX Vessel Prep System™ is an over-the-wire sheathed catheter with a three-strut treatment element near the distal tip.

The FLEX Vessel Prep™ System is advanced over a 0.014” or 0.018” guidewire until distal to the lesion to be treated. The Treatment Element is unsheathed and expanded. The Treatment Element consists of three independent flexible struts, each with a precision blade, mounted on the proximal end. As the device is pulled back in a retrograde fashion through the target lesion, the Treatment Element “flexes” providing continuous engagement along the lesion to create controlled-depth micro-incisions.

The Flex Vessel Prep™ System is available in 2 lengths, 120cm and 40cm. The device has a 2mm crossing profile and is compatible with 6 French introducer sheaths. It is recommended to use a 150 cm+ guidewire with the 40cm product and a 300cm guidewire with the 120cm product.

The device consists of three integrated components. The Control Handle, which contains a Guidewire Port for guidewire insertion, a Flush Port to flush with saline to remove air from the device, the Sheath Actuator and Treatment Element Actuator.

The Sheath Actuator is located on the flat surface of the handle below the word FLEX. When the Sheath Actuator is pulled back and held in place, the sheath covering the Treatment Element is retracted and the Treatment Element is exposed. A click verifies the sheath is fully retracted.

The Treatment Element Actuator is located on the curved aspect of the handle, above the word FLEX. When the Treatment Element Actuator is pulled back and held in place, the Treatment Element expands the 3 flexible struts of the Treatment Element.

The Reinforced Braided Shaft, which is enclosed within a clear polymer sheath, provides strength to enhance deliverability and torque performance of the device.

The distal end of the device contains a radiopaque marker to aid in positioning the catheter and the Treatment Element.

The Treatment Element consists of three precision blades, 10 thousandths of an inch (0.010”) in height and mounted on the proximal end of each of the three independent flexible struts. The expansion of the Treatment Element allows the three precision blades to independently engage the lesion.

During the retrograde pull-back of the device, each strut of the protective Treatment Element “flexes” independently to provide continuous engagement along and through complex lesions to create controlled-depth micro-incisions along the length of the lesion. These micro-incisions modify the plaque in the lesion and enable dilatation of the target lesion using percutaneous angioplasty balloons at lower inflation pressures, minimizing barotrauma to the vessel.
INDICATIONS FOR USE / INTENDED USE

The FLEX Vessel Prep™ System 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. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature.

TECHNOLOGICAL CHARACTERISTICS

At a high level, the subject, reference, and predicate devices are based on the same technological elements.

<table>
<thead>
<tr>
<th>Item</th>
<th>FLEX Vessel Prep™ System</th>
<th>FLEX Vessel Prep™ System</th>
<th>Scoreflex PTA Scoring Balloon Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use/Intended Use</td>
<td>The FLEX Vessel Prep™ System 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. <strong>The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature.</strong></td>
<td>The FLEX Vessel Prep™ System 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.</td>
<td>Similar Addition of ISR indication</td>
</tr>
<tr>
<td>Guidewire compatibility</td>
<td>0.014&quot; or 0.018&quot;</td>
<td>0.014&quot; or 0.018&quot;</td>
<td>Same 0.014&quot; and 0.018&quot;</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Ethylene Oxide</td>
<td>Ethylene Oxide</td>
<td>Same Ethylene Oxide</td>
</tr>
<tr>
<td>Single Use Only</td>
<td>Yes</td>
<td>Yes</td>
<td>Same Yes</td>
</tr>
<tr>
<td>Scoring Member (Treatment Element)</td>
<td>3 Independent precision blades for controlled depth</td>
<td>3 Independent precision blades for controlled depth</td>
<td>Same 2 1 (one) Nitinol Integrated Wire and 1 (one) 0.018&quot; loose guidewire</td>
</tr>
<tr>
<td>Mechanism of Action</td>
<td>Retrograde pull-back of the treatment elements through lesion creates controlled microincisions</td>
<td>Retrograde pull-back of the treatment elements through lesion creates controlled microincisions</td>
<td>Same Focal force of wires against lesion.</td>
</tr>
<tr>
<td>Micro-incision Depth</td>
<td>0.010&quot; ± 0.002&quot;</td>
<td>0.010&quot; ± 0.002&quot;</td>
<td>Same 0.018&quot; Guidewire and 0.014&quot; Uses Nitinol Integral Wire</td>
</tr>
</tbody>
</table>

Traditional 510(k)
<table>
<thead>
<tr>
<th>Item</th>
<th>FLEX Vessel Prep™ System</th>
<th>FLEX Vessel Prep™ System</th>
<th>Scoreflex PTA Scoring Balloon Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scoring Member Depth Control</td>
<td>Yes</td>
<td>Same</td>
<td>No</td>
</tr>
<tr>
<td>Visibility</td>
<td>Radiopaque marker band at distal end</td>
<td>Radiopaque marker band at distal end</td>
<td>Two radiopaque platinum/iridium markers bands are located on scoring wire and aligned with the balloon shoulders</td>
</tr>
<tr>
<td>Integrated Balloon</td>
<td>No</td>
<td>No</td>
<td>Same</td>
</tr>
<tr>
<td>Expansion Mechanism</td>
<td>Operator expanded</td>
<td>Operator expanded</td>
<td>Same</td>
</tr>
<tr>
<td>Scoring Member Expanded Size</td>
<td>120cm device – 4mm ± 1mm, 40cm device - 6mm ± 1mm</td>
<td>120cm device – 4mm ± 1mm, 40cm device - 6mm ± 1mm</td>
<td>Same</td>
</tr>
<tr>
<td>Overall Device Length</td>
<td>40cm, 120cm</td>
<td>40cm, 120cm</td>
<td>Same</td>
</tr>
<tr>
<td>Treatment Element</td>
<td>Stainless steel (nickel-free/high nitrogen stainless steel alloy)</td>
<td>Stainless steel</td>
<td>Similar</td>
</tr>
<tr>
<td>Protective Struts</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PERFORMANCE DATA**

The FLEX Vessel Prep™ System has been tested and meets all its physical and performance specifications for treatment element protective strut material change and in-stent use. Bench testing was performed in accordance with applicable FDA guidance, ASTM and ISO standards.

The testing demonstrated that the device meets specifications before and after distribution and aging indicating that the device is substantially equivalent to the predicate device.

Testing included:

Biological Safety Testing

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility
- Chemical Characterization with Toxicological Risk Assessment

Environmental Conditioning & Distribution

Performance Specifications Testing

Simulated Use Testing

Physical & Dimensional Testing

Packaging & Labeling Testing

**SUBSTANTIAL EQUIVALENCE**

The subject device is equivalent to the predicate device.
CONCLUSION

VentureMed considers the FLEX Vessel Prep™ System to be substantially equivalent to the predicate device listed above for the treatment element protective strut material change and in-stent use indication. The subject devices has the same intended use, principles of operation, and similar design features. Bench testing demonstrate that none of the technical differences raise any new questions of safety and effectiveness.