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,

For

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
FLEX Vessel Prep™ System

Indications for Use *(Describe)*
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)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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. 2800 Campus Drive, Suite 50 Plymouth, MN 55441, USA Phone: 763.951.0280 Fax: 419-558-4171
Primary Submission Contact:	Jill Schweiger Vice President, Clinical, Regulatory, and Quality Assurance VentureMed Group, Inc. 2800 Campus Drive, Suite 50 Plymouth, MN 55441, USA Cell Phone: 612-385-4090 Email: jschweiger@venturemedgroup.com
Secondary Submission Contact:	Sara Petrie Director of Quality Assurance and Regulatory VentureMed Group, Inc. 2800 Campus Drive, Suite 50 Plymouth, MN 55441, USA Cell Phone: 612.396.9849 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.

	FLEX Vessel Prep™ System	**FLEX Vessel Prep™ System**	**Scoreflex PTA Scoring Balloon Catheter**	
510(k) Number	K202187	K152789	K182713	
Manufacturer	VentureMed Group, Inc.	VentureMed Group, Inc.	OrbusNeich Medical Trading, Inc.	
Classification	Class II	Class II	Class II	Same
Product Code	PNO	PNO	PNO	Same
Regulation	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	Same

Item	**FLEX Vessel Prep™ System**	**FLEX Vessel Prep™ System**		**Scoreflex PTA Scoring Balloon Catheter**	
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.**	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.	Similar Addition of ISR indication	The Scoreflex PTA Scoring Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. **This device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature.**	Similar (Predicate is also indicated for iliac, ilio-femoral, infra-popliteal, and renal arteries.)
Guidewire compatibility	0.014” or 0.018”	0.014” or 0.018”	Same	0.014” and 0.018”	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same	Ethylene Oxide	Same
Single Use Only	Yes	Yes	Same	Yes	Same
Scoring Member (Treatment Element)	3 Independent precision blades for controlled depth	3 Independent precision blades for controlled depth	Same	2 1 (one) Nitinol Integrated Wire and 1 (one) 0.018” loose guidewire	Different
Mechanism of Action	Retrograde pull-back of the treatment elements through lesion creates controlled microincisions	Retrograde pull-back of the treatment elements through lesion creates controlled microincisions	Same	Focal force of wires against lesion.	Different
Micro-incision Depth	0.010” ± 0.002”	0.010” ± 0.002”	Same	0.018” Guidewire and 0.014” Uses Nitinol Integral Wire	Different

Item	FLEX Vessel Prep™ System	FLEX Vessel Prep™ System		Scoreflex PTA Scoring Balloon Catheter	
Scoring Member Depth Control	Yes	Yes	Same	No	Different
Visibility	Radiopaque marker band at distal end	Radiopaque marker band at distal end	Same	Two radiopaque platinum/iridium markers bands are located on scoring wire and aligned with the balloon shoulders	Different
Integrated Balloon	No	No	Same	Yes	Different
Expansion Mechanism	Operator expanded	Operator expanded	Same	Balloon Expanding	Different
Scoring Member Expanded Size	120cm device – 4mm ± 1mm 40cm device - 6mm ± 1mm	120cm device – 4mm ± 1mm 40cm device - 6mm ± 1mm	Same	Dependent upon inflated balloon diameter	Different
Overall Device Length	40cm, 120cm	40cm, 120cm	Same	40cm, 90cm, 150cm	Different
Treatment Element Protective Struts	Stainless steel (nickel-free/high nitrogen stainless steel alloy)	Stainless steel	Similar	Not Applicable	Different

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.