November 21, 2019

MicroVention, Inc.,
Mr. Ganesh Balachandar
Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K192625
Trade/Device Name: PG Pro Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: September 20, 2019
Received: September 23, 2019

Dear Mr. Balachandar:

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)*
K192625

Device Name
PG Pro Microcatheter

Indications for Use *(Describe)*
The PG Pro microcatheter is intended for the peripheral vasculature for the infusion of diagnostic and therapeutic agents.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

SUBMITTER

MicroVention Inc.
35 Enterprise, Aliso Viejo, CA 92656
Phone: 714-247-8000
Contact Person: Ganesh Balachandar
Date Prepared: 20th, September 2019

DEVICE

Name of the Device: PG Pro Microcatheter
Common Name: Percutaneous Catheter
Classification Name: Device, Percutaneous Catheter
Regulatory Class: Class II, 21 CFR 870.1250
Product Code: DQY
Additional Product Code: KRA

PREDICATE DEVICE

Headway 27 Microcatheter (K142449)

REFERENCE DEVICE

Headway 17 Microcatheter (K101542)

DEVICE DESCRIPTON

The PG Pro Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the catheter hub is used for the attachment of accessories.

INDICATION FOR USE

The PG Pro Microcatheter is intended for the peripheral vasculature for the infusion of diagnostic and therapeutic agents.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

Table 1: Headway Microcatheters and PG Pro Comparison table				
Property	**Headway 17 Microcatheter** **Reference Device** **(K101542)**	**Headway 27 Microcatheter** **Predicate Device** **(K142449)**	**PG Pro Microcatheter** **Subject Device**	**Differences**
Indication For Use	The Headway 17 Microcatheter is intended for general intravascular use, including the peripheral, coronary and neurovasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	The Headway 27 Microcatheter is intended for general intravascular use, including the peripheral, coronary and neurovasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	The PG Pro microcatheter is intended for the peripheral vasculature for the infusion of diagnostic and therapeutic agents.	The PG Pro Microcatheter is intended only for the peripheral vasculature.
Principle of Operation	The principle of operation incorporates various design features that allow it to achieve its intended use. A semi-rigid proximal section allows for steerability. Progressively softer durometer distal segments and flexible tip allow for atraumatic navigation through the vasculature. Radiopaque markers allow for fluoroscopic visualization. Hydrophilic polymer coating reduces friction	The principle of operation incorporates various design features that allow it to achieve its intended use. A semi-rigid proximal section allows for steerability. Progressively softer durometer distal segments and flexible tip allow for atraumatic navigation through the vasculature. Radiopaque markers allow for fluoroscopic visualization. Hydrophilic polymer coating reduces friction during navigation through the vasculature.	The principle of operation incorporates various design features that allow it to achieve its intended use. A semi-rigid proximal section allows for steerability. Progressively softer durometer distal segments and flexible tip allow for atraumatic navigation through the vasculature. Radiopaque markers allow for fluoroscopic visualization. Hydrophilic polymer coating reduces friction	Identical

Table 1: Headway Microcatheters and PG Pro Comparison table				
Property	**Headway 17 Microcatheter** **Reference Device** **(K101542)**	**Headway 27 Microcatheter** **Predicate Device** **(K142449)**	**PG Pro Microcatheter** **Subject Device**	**Differences**
	during navigation through the vasculature.		during navigation through the vasculature.	
Material(s)	Catheter body: Pebax, stainless steel, Grilamid, inner liner of PTFE and barium sulfate incorporated in distal Pebax segment.	Catheter body: Pebax, stainless steel, Grilamid, inner liner of PTFE	Catheter body: Pebax, Tungsten, Grilamid, inner liner of PTFE	PG Pro has a Tungsten coil versus a Stainless-steel coil for the Headway 27 and Headway 17 Microcatheters.
	Marker band: Pt/Ir	Marker band: Pt/Ir	Marker band: Pt/Ir	Identical
	Hub: Nylon	Hub: Nylon	Hub: Nylon	Identical
	Strain relief: Pebax	Strain relief: Pebax	Strain relief: Pebax	Identical
	Introducer: Pebax	Introducer: Pebax	Introducer: Pebax	Identical
	Shaping mandrel: Stainless steel	Shaping mandrel: Stainless steel	Shaping mandrel: N/A	PG Pro does not come with a Shaping mandrel.
Proximal ID/OD	ID = .0170" min OD = .031"	ID = .027" min OD = .040"	ID = .027" min OD = .038"MAX	PG Pro has a Max Proximal O.D of .038" which is in-between Headway 17 and

Table 1: Headway Microcatheters and PG Pro Comparison table				
Property	**Headway 17 Microcatheter** **Reference Device** **(K101542)**	**Headway 27 Microcatheter** **Predicate Device** **(K142449)**	**PG Pro Microcatheter** **Subject Device**	**Differences**
				27 Microcatheter proximal OD.
Distal ID/OD	ID = .0170" min OD = .022"	ID = .027" min OD = .034"	ID = .027" min OD = .038" MAX	PG Pro has a Max Distal O.D of .038"
No. of Marker bands	2	2	2	Identical
Coating	Hydrophilic Coating	Hydrophilic Coating	Hydrophilic Coating	Identical
Effective Length	150 cm	150 cm and 156 cm	140 cm and 165 cm	PG Pro comes in two lengths – 140 and 165 cm.
Tip Configuration	Preshaped tips –with the option of secondary shaping for proper adjustment to the anatomy prior to use.	Straight – Steam Shapeable by physician prior to use	Straight configuration	PG Pro is available only in the straight configuration.
Guidewire Compatibility	0.014 "wires or smaller	0.014 "wires or smaller	0.021 "wires or smaller	PG Pro is compatible with 0.021" wires or smaller
Method of supply	Sterile and single use	Sterile and single use	Sterile and single use	Identical
Accessories	Shaping mandrel and Introducer sheath	Shaping mandrel and Introducer sheath	Introducer sheath	PG Pro does not include shaping mandrel

PERFORMANCE DATA

Biocompatibility testing
Biocompatibility evaluation for the PG Pro Microcatheter was conducted in accordance with ISO10993-1 Biological Evaluation of Medical Devices-Part 1: Guidance on Selection of Tests. The microcatheter is considered a limited (<24hour) circulating blood contacting device.

The battery of testing for the device included the following tests:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility

Bench testing
Bench testing conducted for the PG Pro Microcatheter included the following:

- Surface Contamination
- Physical Attributes
- Force at break (Hub and distal portion of the catheter)
- Liquid leakage
- Air leakage
- Static burst
- Durability and lubricity of hydrophilic coating
- Simulated use in flow model
- Dynamic burst
- Catheter flow rate
- Kink resistance
- Stiffness testing
- Catheter flexural fatigue
- Particulate testing
- Catheter dead space
- Torque strength
- Hub testing
- Corrosion testing
- Radio detectability

Animal Study
The PG Pro Microcatheter was evaluated in an acute large animal study (n=3) The safety profile as assessed through device safety, compatibility with therapeutic agents and tissue response showed that the PG Pro Microcatheter performed similar to the predicate device, Headway 27 Microcatheter.

CONCLUSION

The PG Pro Microcatheter is substantially equivalent to the identified predicate regarding performance, intended use, design, materials, principle of operation and overall technological characteristics. The nonclinical data supports the substantial equivalence of the subject device and the verification and validation testing demonstrate that the subject device should perform as intended when used as instructed in the instructions for use.