December 24, 2019

MicroVention, Inc.
Sapna Singh
Associate Director, Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K192135
Trade/Device Name: VIA® Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: November 22, 2019
Received: November 25, 2019

Dear Sapna Singh:

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,

Xiaolin Zheng, Ph.D., M.S.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K192135

Device Name
VIA® Microcatheter

Indications for Use *(Describe)*
VIA 21, 27, 33 - The VIA® Microcatheter is intended for the introduction of interventional devices (such as the WEB device/stents/flow diverters) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature.

VIA 17, 17 Preshaped 45°, 17 Preshaped 90° - The VIA® Microcatheter is intended for the introduction of interventional devices (such as coils/stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary 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.

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510(K) SUMMARY

I. SUBMITTER

MicroVention Inc.
35 Enterprise, Aliso Viejo, CA 92656
Phone: 714-247-8162
Fax: 714-439-1044
Contact Person: Sapna Singh
Date Prepared: November 22, 2019

II. DEVICE

Name of Device	VIA® Microcatheter
Common Name	Catheter, Percutaneous
Classification Name	Percutaneous Catheter (21 CFR 870.1250) Continuous Flush Catheter (21 CFR 870.1210)
Regulatory Class	Class II
Classification Product Code	DQY
Subsequent Product Code	KRA

III. PREDICATE DEVICE

VIA® Microcatheter (K150894, K132652, K162565) manufactured by Sequent Medical Inc. (SMI).

IV. REFERENCE DEVICE

Headway Microcatheter (K101542, K110813) manufactured by MicroVention Inc. (MVI)

Scepter C Balloon Catheter (K110741, K121785) manufactured by MicroVention Inc. (MVI)

V. DEVICE DESCRIPTON

The VIA® Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The physician inserts the catheter into the vein or artery through the skin (percutaneous) using a sheath or guidewire. The device can then be navigated to the treatment site. Navigation is aided by the coated surface of the catheter which assists with manipulation while in the vasculature. Throughout the procedure the physician can obtain the position of the catheter by the radiopaque marker bands using fluoroscopic techniques (VIA17 Microcatheter has 2 radiopaque marker bands. VIA 21, 27 and 33 Microcatheters have one radiopaque tip marker band). Diagnostic and interventional devices can be delivered through the

lumen of the catheter to the treatment site. The proximal end of the catheter incorporates a standard luer adapter to facilitate attachment of accessories.

VI. INDICATION FOR USE

VIA 21, 27, 33 - The VIA® Microcatheter is intended for the introduction of interventional devices (such as the WEB device/stents/flow diverters) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature.

VIA 17, 17 Preshaped 45°, 17 Preshaped 90° - The VIA® Microcatheter is intended for the introduction of interventional devices (such as coils/stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature.

VII. TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

	Headway Microcatheter	**SMI VIA Microcatheter**	**MVI VIA Microcatheter**
	Reference Device **Headway 17 Advanced (K101542) Headway 27 (K110813)**	**Predicate Device** **VIA17 (K162565) VIA21 (K150894) VIA27 & 33 (K132652)**	**Subject Device**
Intended Use	The Headway Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	VIA21, 27, 33: The VIA Catheter is intended for the introduction of nonliquid interventional devices (such as stents/flow diverters) and infusion of diagnostic (such as contrast media) or non-liquid therapeutic agents into the neuro, peripheral, and coronary vasculature. The VIA 17 Microcatheter is intended for the introduction of non-liquid interventional devices (such as coils/stents) and	VIA 21, 27, 33 - The VIA® Microcatheter is intended for the introduction of interventional devices (such as the WEB device/stents/flow diverters) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature. VIA 17, 17 Preshaped 45°, 17 Preshaped 90° - The VIA® Microcatheter is intended for the introduction of interventional devices

		infusion of diagnostic agents (such as contrast media) neuro, peripheral, and coronary vasculature.	(such as coils/stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature.
Device Classification	Class II DQY 21 CFR 870.1250	Class II DQY, KRA 21 CFR 870.1250 21 CFR 870.1210	Class II DQY, KRA 21 CFR 870.1250 21 CFR 870.1210
Catheter Body	Outer layer of Pebax and Grilamid; inner layer PTFE. Between outer and inner layer is stainless steel coil.	Outer layer of Pebax and Vestamid; inner layer PTFE. Between outer and inner layer is stainless steel braid and coil.	Same as SMI VIA Microcatheters
Marker	Platinum/Iridium	Platinum/Iridium	Same as SMI VIA Microcatheters
Hub	Nylon	Polypropylene	Same as SMI VIA Microcatheters
Strain Relief	Pebax	Polyolefin	Same as SMI VIA Microcatheters
Introducer	Pebax	Pebax	Same as Headway Microcatheters
Shaping Mandrel	Stainless steel	Stainless steel	Same as Headway Microcatheters
Catheter size (OD Distal)	Headway 17 Advanced: 0.022” Headway 27: 0.034”	VIA17: 2.2F (0.029”) VIA21: 2.5F (0.033”) VIA27: 3.0F (0.039”) VIA33: 3.4F (0.045”)	Same as SMI VIA Microcatheters

ID	Headway 17 Advanced: 0.017” Headway 27: 0.027”	VIA17: 0.0175” VIA21: 0.021” VIA27: 0.027” VIA33: 0.033”	Same as SMI VIA Microcatheters
OD Proximal	Headway 17 Advanced: 0.031” Headway 21: 0.040”	VIA17: 0.032” VIA21: 0.036” VIA27: 0.042” VIA33: 0.050”	Same as SMI VIA Microcatheters
Effective Length	150 cm	VIA17: 154 cm VIA21: 154 cm VIA27: 154 cm VIA33: 133 cm	Same as SMI VIA Microcatheters
Coating	Hydronic Acid (Hydrophilic Coating) – 100cm	Polyvinylpyrrolidone (Hydrophilic Coating) – 100 cm	Same as Headway Microcatheters – 100 cm
Tip Configuration	Headway 17 Advanced: Straight & Preshaped Headway 21: Straight	Straight	VIA17: Straight & Preshaped VIA21, 27, 33: Straight
Guidewire Compatibility	Headway 17 Advanced: 0.014” OD or smaller Headway 21: 0.018” OD or smaller	VIA17: 0.014” OD or smaller VIA21, 27, 33: 0.018” OD or smaller	Same as SMI VIA Microcatheters
Accessories	Introducer sheath and shaping mandrel	Shaping mandrel	Same as Headway Microcatheters
Method of Supply	Sterile and single use	Sterile and single use	Same as SMI VIA & Headway Microcatheters
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same as SMI VIA & Headway Microcatheters

Packaging Configuration	Catheter placed into a HDPE dispenser coil. Introducers sheath and shaping mandrel placed on a polyethylene packaging card that is attached to the dispenser coil. Dispenser coil is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box.	Catheter placed into a HDPE dispenser coil. Shaping mandrel placed on a polyethylene packaging card that is attached to the dispenser coil. Dispenser coil is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box.	Same as Headway Microcatheters

VIII. PERFORMANCE DATA

Biocompatibility testing
Biocompatibility evaluation for the VIA® Microcatheter was conducted in accordance with "Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The microcatheter is considered a limited (<24hour) circulating blood contacting device.

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

Test Performed	**Extract(s) & Test Systems**	**Extract Conditions**	**Results**
Cytotoxicity (ISO Medium Eluate Method (MEM) Elution Test)	Eagle's Minimal Essential Medium (E-MEM) + 5% Fetal Bovine Serum (FBS) L929 Mouse Fibroblast Cell Line	6.0 cm^2/mL Extracted at 37°C/24 hrs.	Non-cytotoxic The test article is considered non-cytotoxic to cells.
Sensitization (ISO Guinea Pig Maximization Sensitization Test)	Normal Saline and Sesame Oil Extracts Hartley Guinea Pigs (17 Male)	6.0 cm^2/mL Extracted at 70°C/24 hrs.	Non-sensitizing The test article did not elicit a sensitization response.
Irritation/ Intracutaneous Toxicity (ISO Intracutaneous Irritation Test)	Normal Saline and Sesame Oil Extracts New Zealand White Rabbits (3 Female – non-pregnant and nulliparous)	6.0 cm^2/mL Extracted at 70°C/24 hrs.	Non-irritant No evidence of irritation.

Acute Systemic Toxicity (ISO Acute Systemic Injection Test)	Normal saline and Sesame Oil Extracts Albino Swiss Mice (20 Female – non-pregnant and nulliparous)	6.0 cm^2/mL Extracted at 70°C/24 hrs.	Systemically non-toxic No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice.
Material-Mediated Pyrogenicity	Normal Saline New Zealand White Rabbits (3 Female – non- pregnant and nulliparous)	6.0 cm^2/mL Extracted at 70°C/24 hrs.	Non-pyrogenic All individual rabbits injected with the test article showed a total rise in temperature of < 0.5 ºC and were determined to be non-pyrogenic.
Hemocompatibility (ASTM Hemolysis Assay – Direct Contact and Indirect Contact)	Direct Contact Solid Sample Exposure to Rabbit Blood Substrate and Indirect Contact Extracted in Phosphate Buffered Saline (PBS) Blood from 3 New Zealand White Rabbits	Direct Contact: 6.0 cm^2/mL exposure to Blood Substrate then incubated at 37ºC for 3 hours with approximately 60 RPM agitation. Indirect Contact: 6.0 cm^2/mL in PBS extracted at 70°C for 24 hours then extract exposed to blood substrate and incubated at 37ºC for 3 hours with approximately 60 RPM agitation.	Non-hemolytic There were no significant differences between the test article extract/solid and negative control article results.
Hemocompatibility (Partial Thromboplastin Time (PTT) with Sponsor-Supplied Comparison Article)	Solid Sample Exposure to Human Plasma	6.0 cm^2/mL Incubated with human plasma at 37ºC for 15 minutes with orbital shaking at approximately 60 RPM.	No adverse effect on Unactivated Partial Thromboplastin Time of human plasma. The solid test article was determined to be compatible with blood and not affect coagulation.

Hemocompatibility (ISO Complement Activation C3a and SC5b-9 Assay with Sponsor-Supplied Comparison Article)	Solid Sample and Normal Human Serum (NHS) as exposure medium	6.0 cm^2/mL of NHS at 37ºC for 60 minutes.	C3a and SC5b-9 complement proteins were considered to be non-activated as compared to the comparison article.
Hemocompatibility (Platelet and Leukocyte Counts with Sponsor-Supplied Comparison Article)	Solid Sample exposure to Whole Human Blood medium	12 cm^2/mL whole blood at 37ºC for 60 minutes with agitation at approximately 60 RPM.	Platelet count for the test article exposed blood are not statistically significantly different as compared to reference control or comparison article.
Hemocompatibility (Thromboresistance Evaluation)	Test and Control device surgically placed at each jugular vein of the animal. 2 Canine, Cross bred hound – Female: nulliparous and non-pregnant.	Direct Exposure for 4 hours.	Non-thrombogenic
Genotoxicity (ISO Bacterial Mutagenicity Test – Ames Assay)	Normal Saline And Dimethylsulfoxide (DMSO) Ames Assy - Salmonella. typhimurium TA97a, TA98, TA100, TA1535, and E. coli WP2 uvr A under both non-activated and activated Systems	6.0 cm^2/mL Extracted at 70°C/24 hrs.	Non-mutagenic
Genotoxicity (ISO In Vitro Mouse Lymphoma with Extended Treatment	Normal Saline And Dimethylsulfoxide (DMSO) L5178Y mouse lymphoma cells	6.0 cm^2/mL Extracted at 70°C/24 hrs. Extracts contact with test system for 4 hours in non-activated and activated conditions	Non-mutagenic and non-clastogenic

		and 24 hours in non-activated condition.	

The biocompatibility of the VIA® Microcatheter accessories, introducer sheath and shaping mandrel are supported by information submitted for the cleared MicroVention Headway Microcatheter (K101542, K110813) and MicroVention Scepter C Balloon Catheter (K110741, K121785) devices. The VIA accessories are identical to the accessories included in the cleared Headway and Scepter devices.

Bench testing
Bench testing conducted for the VIA® Microcatheter included the following:

Test	**Test Method Summary**	**Results**
Visual and Dimensional Inspection	This method measures inner diameter, outer diameter, catheter length, coated length, tip length, distance between marker bands (VIA17 only), preshaped tip angle (VIA17 Preshaped only), printing on strain relief, accessories, and unbraided length.	Pass
Hub ISO 80369-7	ISO80369-7:2016 & -20:2015	Pass
WEB Retraction	The method measures the distance that the VIA catheter pulls back during interventional device recapture	Pass
Kink Resistance	The method measures the diameter at which the VIA shaft sections and junctions will kink	Pass
Tensile	The method tests the tensile strength of the microcatheter shaft sections (each joint/transition tested individually). This method aligns with the method described in ISO 10555-1:2014.	Pass
Tip Buckling	The method measures the catheter tip buckling force by pushing the catheter tip into a load cell until it buckles.	Pass
Steam Shaping / Shape Retention	The method measures the ability of the VIA to be steam shaped using a shaping mandrel and the ability of the VIA to hold the shape during use.	Pass
Catheter Leakage and Static Burst	The method measures the leakage and static burst pressure of the VIA. This method aligns with the method described in ISO 10555-1:2014.	Pass

Coating Friction & Durability	The method measures the catheter coating friction/lubricity over multiple friction test cycles using an automated friction tester. After cycling, catheter is dyed to verify coating adherence.	Pass
Coating Particulate	The method measures the particulate generated during simulated navigation and adjunct device delivery per USP <788>.	Pass
Coating Integrity	Coating integrity uses dye to test that coating remains adhered to catheter after simulated use through a tortuous model.	For characterization only.
Catheter Torque Strength	The method measures how many complete rotations the catheter can withstand before breaking.	For characterization only.
Tracking Force	The method tests the force required to pass interventional devices through the VIA catheter.	Pass
Flow Rate	The method measures the flow rate through the VIA by pushing fluid through the catheter at a constant rate while pressure is being monitored.	For characterization only.
Dead Space	The non-hydrated VIA is attached to a syringe pump and slowly filled with controlled amounts of distilled water. Once water is observed to be exiting the raised tip of the catheter, the volume of liquid dispensed is recorded.	For characterization Only

Animal Study
No animal study was conducted.

IX. CONCLUSION
The VIA® 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.