January 10, 2023

MicroVention, Inc.
Sona Manickam
Manager Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K222115
Trade/Device Name: ISAAC Neurovascular Navigation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: December 9, 2022
Received: December 9, 2022

Dear Sona Manickam:

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222115

Device Name
ISAAC™ Neurovascular Navigation Catheter

Indications for Use *(Describe)*
The ISAAC™ Neurovascular Navigation Catheter is indicated for use in facilitating advancement of catheters through the neuro and peripheral vasculature and introduction of diagnostic agents. The ISAAC™ Neurovascular Navigation Catheter is not intended for use in the 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.

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."

K222115 510(k) Summary

510(k) Owner	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 Establishment Registration No: 3013556777
Contact Person	Sona Manickam Manager Regulatory Affairs Telephone: (712)-582-8133 Email: Sona.Manickam@microvention.com
Date Summary Prepared	January 09, 2023
Trade Name	ISAAC™ Neurovascular Navigation Catheter
Common Name	Catheter, Percutaneous
Classification	Class II, DQY, QJP
Regulation	21 CFR 870.1250
Predicate Device	Chaperon Guiding Catheter (K082385)
Reference Devices	Neuron Select Catheter (K083125)
	Neuron MAX System (K111380)

Device Description

The ISAAC™ Neurovascular Navigation Catheter (ISAAC Catheter) is a braid-reinforced variable stiffness catheter with a pre-shaped distal segment. The distal end of the catheter is coated with a hydrophilic coating around the curve of the pre-shaped section of the Simmons (SIM) configuration. It is a single lumen catheter with a radiopaque distal coiled section and a Luer hub on the proximal end. The ISAAC Catheter is sterile, non-pyrogenic and intended for single use only.

Indications for Use

The ISAAC™ Neurovascular Navigation Catheter is indicated for use in facilitating advancement of catheters through the neuro and peripheral vasculature and introduction of diagnostic agents. The ISAAC™ Neurovascular Navigation Catheter is not intended for use in the coronary vasculature.

Comparison of Indications for Use and Technological Characteristics

The subject device, ISAAC Catheter, and the predicate device, the inner catheter of the Chaperon Guiding Catheter (K082385) are substantially equivalent in that these devices have similar intended use, principles of operation, and fundamental design.

As evidenced by the data, the subject, predicate, and reference devices:

- have similar intended use,
- use the same principles of operation,
- incorporate the same basic design,
- use similar construction and materials,
- are Ethylene Oxide (EtO)- sterilized and packaged using the same processes.

The following table provides a comparison of the key characteristics of the ISAAC Catheter to the predicate and reference devices.

Device Comparison Table

Device Characteristics	Proposed Device ISAAC Neurovascular Navigation Catheter (K222115)	Predicate Device Chaperon Guiding Catheter (K082385)	Reference Device Neuron Select Catheter (K083125)
Indications for Use	The ISAAC Neurovascular Navigation Catheter is indicated for use in facilitating advancement of catheters through the neuro and peripheral vasculature and introduction of diagnostic agents. The ISAAC Neurovascular Navigation Catheter is not intended for use in the coronary vasculature.	Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.	The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature.
Device Class	Class II DQY, QJP 21 CFR 870.1250	Class II DQY 21 CFR 870.1250	Class II DQY 21 CFR 870.1250
Catheter Body	Braid: Stainless Steel Catheter: Polytetrafluoroethylene (PTFE) Coiling: Tungsten Outer: Polymer	Braid: Stainless Steel Catheter: PTFE	Braid: Stainless Steel Catheter: PTFE
Marker	Radiopaque coil	Radiopaque marker	Radiopaque jacket
Hub	Nylon	Nylon	Nylon
Strain Relief	Polyurethane	Polyurethane	Polyurethane
Inner Diameter	6F: 1.02 mm (0.040”)	5F: 1.22 mm (0.048”)	6F: 1.02 mm (0.040”)
Outer Diameter	6F: 2.11 mm (0.083”)	5F: 1.70 mm (0.067”)	6.5F: 2.16 mm (0.085”)
Effective Length	SIM2-3D: 150 cm SIM3-3D: 150 cm TIP45: 140 cm	117 cm	125 cm
Coating	Hydrophilic	Hydrophilic	Hydrophilic
Tip Configuration	Variable Tip Shape & Size	Variable Tip Shape & Size	Variable Tip Shape & Size
Guidewire Compatibility	0.035” and 0.038”	0.035” and 0.038”	0.035” and 0.038”
Accessories	Not applicable	Not applicable	Not applicable
Method of Supply	Sterile and single use	Sterile and single use	Sterile and single use
Sterilization Method	Sterilized using 100% Ethylene Oxide	Sterilized using 100% Ethylene Oxide	Sterilized using 100% Ethylene Oxide

Device Characteristics	Proposed Device	Predicate Device	Reference Device
	ISAAC Neurovascular Navigation Catheter (K222115)	**Chaperon Guiding Catheter (K082385)**	**Neuron Select Catheter (K083125)**
Packaging Configuration	Placed on mounting card, Tyvek pouch, shipping carton	Placed on mounting card, Tyvek pouch, shipping carton	Placed on mounting card, Tyvek pouch, shipping carton

Performance Testing Summary

The following performance testing was conducted to support the design of the ISAAC Catheter and demonstrate that it performs as intended:

Test	Test Method Summary	Results
Physical Attributes	The usable length, proximal and distal outer diameters, distal length, and inner diameters were measured.	Pass
Tip Flexibility	The device shall have less force to bend at the distal tip than the comparator reference device.	Pass
Simulated Use	The performance of the catheter was rated during simulated-use testing in benchtop vessel model.	Pass
Radio Detectability	The catheter must be visible under X-ray fluoroscopy.	Pass
Kink Resistance	Kink resistance was measured by subjecting the device to bending in simulated tortuous anatomy.	Pass
Static Burst	The distal tip of the catheter was occluded, and fluid was injected into the lumen at increasing pressure until the catheter burst.	Pass
Liquid Leakage	The distal tip of the catheter was occluded, and fluid was injected. Pressure was maintained for 30 seconds, and the device was inspected for leakage per ISO 10555-1.	Pass
Leakage and Damage Under High Static Pressure Conditions	Dyed fluid was injected into the lumen until the rated burst pressure was reached and the pressure was held for 10 seconds while the distal tip is occluded.	Pass
Air Leakage	A vacuum was applied to the catheter and observed for air bubbles, per ISO 80369-7 and ISO 10555-1.	Pass
Dynamic Burst	The catheter was injected with fluid at a set pressure and inspected for damage.	Pass
Force at Break (Hub/Distal)	The distal and proximal sections of the catheter are secured into a tensile test machine. The machine pulled until the catheter broke, and the pull force was recorded.	Pass
Particulate Testing	The catheter underwent simulated-use testing in a benchtop model and was evaluated for particulates.	Pass
Surface Contamination	Device must be free from visible surface defects.	Pass
Corrosion Resistance	The catheter was tested to evaluate corrosion resistance per ISO 10555-1 and ISO 11070.	Pass
Coating Durability and Lubricity	Device was secured to a tensile machine and put into heated water bath for hydration. The force to slide through the clamp was recorded as lubricity through 20 cycles. Durability was recorded through 100 cycles.	Pass
Catheter Flexural Fatigue	The tensile strength and pressure characteristics were measured per ISO 10555-1.	Pass

Test	Test Method Summary	Results
Hub and Luer Connector	The Luer connector was tested to dimensional and performance requirements per ISO 80369-7.	Pass
Stiffness	The catheter stiffness profile was compared to the reference device.	Pass
Torque Strength	The device was evaluated for torque strength by measuring the number of catheter rotations until failure after tracking through a tortuous anatomical model.	Pass

Biocompatibility Testing Summary

The biological safety of the ISAAC Catheter was verified in accordance with ISO 10993-1 categorized as an externally communicating device directly contacting circulating blood for a limited duration (≤ 24 hours). All ISAAC Catheter materials have a history of use in medical devices. The table below illustrates specific tests performed.

Test Method Summary			
Test	**Extract(s) & Test Systems**	**Extraction Conditions**	**Results**
Cytotoxicity (ISO MEM Elution Test)	L-929 mouse fibroblast cells prepared using MEM Maintenance Growth Media with 5% FBS	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 37 °C for 24 hrs.	Non-cytotoxic
Irritation Reactivity (ISO Intracutaneous Reactivity Test)	Normal saline and sesame seed oil (SSO) (tested separately) New Zealand White Rabbits	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 ± 2°C for 72 ± 2hrs.	Non-irritant
Maximization (ISO Guinea Pig Maximization Test)	Normal saline and SSO (tested separately)	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 ± 2°C for 72 ± 2hrs.	Non- sensitizing
Systemic Toxicity (ISO Acute Systemic Toxicity Test)	Normal Saline and SSO (tested separately) Albino outbred strain (ND4) mice (20 male, young adults)	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 ± 2°C for 72 ± 2hrs.	Non-acute systemically toxic
Pyrogenicity (ISO/USP Material Mediated Pyrogenicity Test)	Normal saline and SSO (tested separately) New Zealand White Rabbits	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 ± 2°C for 72 ± 2hrs.	Non- pyrogenic

Test Method Summary			
Test	**Extract(s) & Test Systems**	**Extraction Conditions**	**Results**
Hemocompatibility In-Vitro Blood Loop Assay (ISO In-Vitro Blood Loop Assay)	A loop system circulated with freshly drawn sheep blood	Direct exposure at 37±2°C for 4 hours ± 30 minutes.	Thrombogenic risk potential similar to the predicate
Hemocompatibility Hemolysis Assay (ISO ASTM Hemolysis Assay)	Phosphate Buffered Saline (PBS) New Zealand White Rabbits	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 ± 2°C for 72 ± 2hrs.	Non- hemolytic
Hemocompatibility Complement Activation Assay (ISO Hemocompatibility: Complement Activation Assay (C3a and SC5b-9))	Normal Human Serum (NHS)	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio) extracted at 37±2°C for 60 min ± 1 minute.	Non-activator of complement system
Hemocompatibility Partial Thromboplastin (ISO Hemocompatibility: Partial Thromboplastin Time (PTT) Assay)	Human Plasma	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio) extracted at 37±2°C for 60 min ± 1 minute.	No effect on the PTT
Hemocompatibility Heparinized Blood Platelet and Leukocyte (Hemocompatibility: Heparinized Blood Platelet and Leukocyte Count Assay)	Human Blood	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio) extracted at 37±2°C for 60 min ± 1 minute.	Pass

Animal Study

Acute animal testing was conducted in accordance with FDA Good Laboratory Practice (GLP) Regulation (21 CFR Part 58) comparing the ISAAC Catheter to the predicate Chaperon Guiding Catheter and testing with the BOBBY Guiding Catheter. The testing was intended to assess preclinical safety and efficacy for ISAAC Catheter (test article) and the inner catheter of the Chaperon Guiding Catheter (control article) in a porcine model. The porcine model was chosen since the vessel sizes of the pig model allow for insertion and navigation of standard-sized devices used in humans; porcine vessel diameters are comparable with human vasculature. The test article performed comparably to the control article with regards to tracking performance, support, and safety in this acute in vivo model. No significant device-associated complications (dissection, perforation, embolic debris, thrombus formation, hemorrhage, ischemia, necrosis, fibrin deposition, inflammation, internal elastic lamina (IEL) rupture, external elastic lamina (EEL) rupture, mineralization, neointimal maturation, medial injury/fibrosis and adventitial injury/fibrosis) were noted in any of the test article and control article treated vessels. The tracking results demonstrated that the ISAAC Catheter and the Chaperon Guiding Catheter performed equally. The results of the present study did not raise any safety issues with either the test ISAAC Catheter or control Chaperon Guiding Catheter. The devices are deemed equivalent.

Clinical Testing: No clinical testing was deemed necessary to support the substantial equivalence of the ISAAC Catheter.

Conclusion

MicroVention concludes through a review of the benchtop testing, non-clinical animal study assessments, the comparison of the device classification, indications for use, operating principles, technological characteristics, sterility, and biocompatibility testing that the ISAAC Neurovascular Navigation Catheter is substantially equivalent to the predicate Chaperon Guiding Catheter (K082385). Any differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.