September 12, 2022

MicroVention, Inc.
Alick Tan, Ph.D.
Senior Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K214024
Trade/Device Name: SOFIA 88 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: August 12, 2022
Received: August 12, 2022

Dear Alick Tan:

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, 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)*
K214024

Device Name
SOFIA 88 Catheter

Indications for Use *(Describe)*
The SOFIA 88 Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA 88 Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA 88 Catheter is not intended for use in coronary arteries.

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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K214024 510(k) Summary

510(k) Owner	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 Establishment Registration No: 3013556777
Contact Person	Alick Tan, PhD Senior Regulatory Affairs Specialist Telephone: 949-615-2603 Email: alick.tan@microvention.com
Date summary Prepared	September 12, 2022
Trade Name	SOFIA 88 Catheter
Common Name	Catheter, Percutaneous, Neurovasculature
Classification	Class II, DQY, QJP
Regulation	21 CFR 870.1250
Predicate Device	Sofia 6F PLUS/Distal Access Catheters (K150366)
Reference Device	TracStar™ Large Distal Platform; ZOOM™ 88 Large Distal Platform; ZOOM™ 88-T Large Distal Platform (K203764)

Device Description

The SOFIA 88 Catheter is a non-tapered, single-lumen, flexible catheter equipped with coil and braid reinforcement. The distal segment is designed to facilitate vessel selection with 60 cm of distal-shaft hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy.

Indications for Use

The SOFIA 88 Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA 88 Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA 88 Catheter is not intended for use in coronary arteries.

Comparison of Indications for Use and Technological Characteristics

Substantial equivalence of the SOFIA 88 Catheter to the predicate Sofia 6F PLUS/Distal Access Catheters (SOFIA 6F DAC) and to the reference device TracStar Large Distal Platform; ZOOM 88 Large Distal Platform; ZOOM 88-T Large Distal Platform (ZOOM 88) was established through an evaluation of the intended use, indications for use, principles of operation, device design, materials of construction, and an assessment of usability, safety, and effectiveness via bench and animal studies.

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA 88 Catheter compared with the predicate device SOFIA 6F DAC (K150366) and the reference device ZOOM 88 (K203764).

The devices:

- have the same intended use,
- use the same principle of operation,
- incorporate the same basic design,
- use similar construction and material, and
- are ethylene oxide (EtO)-sterilized and packaged using the same processes.

Device Comparison Table

	ZOOM 88 (K203764)	**SOFIA 6F DAC (K150366)**	**SOFIA 88 Catheter**
	Reference Device	**Predicate Device**	**Subject Device**
Indications for Use	The ZOOM 88 and ZOOM 88-T Large Distal Platform are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The SOFIA PLUS/Distal Access Catheters are indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.	The SOFIA 88 Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA 88 Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA 88 Catheter is not intended for use in coronary arteries.
Device Classification	Class II QJP, DQY 21 CFR 870.1250	Class II DQY, DQO 21 CFR 870.1250 21 CFR 870.1200	Class II DQY, QJP 21 CFR 870.1250

	ZOOM 88 (K203764)	SOFIA 6F DAC (K150366)	SOFIA 88 Catheter
	Reference Device	**Predicate Device**	**Subject Device**
Catheter Body	Commonly used medical grade plastics & metals with hydrophilic coating	Outer layer of polyurethane elastomer, polyether block amide, and polyamide; inner layer of metal braid/coil, PTFE, and polyolefin elastomer	Outer layer of polyurethane elastomer (different polyurethane formulation), polyether block amide, and polyamide; inner layer of metal braid/coil, PTFE, and polyolefin elastomer
Marker	-	Platinum/Iridium	Same as SOFIA 6F DAC (K150366)
Hub	-	Nylon	Same as SOFIA 6F DAC (K150366)
Strain Relief	-	Polyurethane	Same as SOFIA 6F DAC (K150366)
Introducer	None	Pebax®	Fluorinated ethylene propylene
Shaping Mandrel	None	Stainless steel	None
Catheter size	8F	6F	8F, Same as ZOOM 88 (K203764)
ID	0.088 in (2.2 mm)	0.070 in (1.8 mm)	0.0875 in (2.22 mm) min
OD	0.110 in (2.79 mm) max	0.0825 in (2.10 mm)	Proximal: 0.108 in (2.74 mm) max Distal: 0.102 in (2.59 mm) max
Effective Length	80–110 cm	115, 125, 131, 135 cm	115 cm
Coating	Hydrophilic coating	Hydrophilic coating	Same as SOFIA 6F DAC (K150366)
Tip Configuration	Beveled distal edge, soft, flexible, atraumatic tip	Straight	Same as SOFIA 6F DAC (K150366)
Guidewire Compatibility	≤ 0.038 in	0.035 in	≤ 0.038 in
Accessories	Rotating hemostasis valve (RHV)	Introducer sheath and shaping mandrel	Introducer sheath

	ZOOM 88 (K203764)	SOFIA 6F DAC (K150366)	SOFIA 88 Catheter
	Reference Device	**Predicate Device**	**Subject Device**
Condition Supplied	Sterile and single use	Sterile and single use	Same
Sterilization Method	EtO	EtO	Same
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek pouch. Pouch and IFU placed in bleached sulfate carton box.	Catheter placed into a HDPE dispenser tube. Dispenser tube and introducer placed on a polyethylene packaging card that is inserted into a Tyvek pouch. Pouch and IFU placed in bleached sulfate carton box.

Performance Testing

Performance testing was conducted to demonstrate the substantial equivalence of the SOFIA 88 Catheter to the predicate device.

The following testing data were provided to evaluate the performance of the SOFIA 88 Catheter.

Test	Test Method Summary	Results
Dimensional Verification	Dimensional specifications were verified by measuring the catheter length, proximal and distal outer diameters, and distal inner diameter.	Pass
Coating Lubricity and Durability	The hydrophilic coating was evaluated for frictional force and durability.	Pass
Simulated Use	Performance was evaluated under simulated use in a tortuous anatomical model to assess preparation, introduction, tracking, and support of the device.	Pass
Dynamic and Static Burst Pressure	Device was subjected to rated burst pressures to test catheter integrity.	Pass

Test	Test Method Summary	Results
Air Leakage	Device was tested for air leakage requirements.	Pass
Liquid Leakage	Device was tested for liquid leakage requirements.	Pass
Tensile Strength	Device was tensile tested to failure, and recorded the force at breakage.	Pass
Flexural Fatigue	Device was subjected to flexural fatigue from repeated bending during simulated use testing and flexural fatigue from repeated hoop stress on the catheter from pressure testing.	Pass
Particulate Testing	The number and size of particulates generated during simulated use in a tortuous anatomical model were measured and results were compared with the predicate device.	Pass
Kink Resistance	Device was evaluated for kink resistance after simulated use testing.	Pass
Torque Strength	Device was evaluated for torque strength by measuring the number of catheter rotations until failure after tracking through a tortuous anatomical model.	Pass
Radio Detectability	Device visibility was evaluated under fluoroscopy.	Pass
Corrosion Resistance	Device corrosion was evaluated after immersion in saline.	Pass
Small-bore Connector	The luer connector was evaluated for dimensional and performance requirements per reference standard.	Pass
Stiffness Profile	The catheter stiffness profile along proximal and distal sections was compared to the reference device.	Pass

Biocompatibility Results

Test	Test Method Summary		Results
	Extract(s) & Test Systems	Extract Conditions	
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 °C for 72 hrs	Non-irritant
Maximization **(ISO Guinea Pig Maximization Test)**	Normal saline and sesame seed oil (SSO) (tested separately) Guinea Pig	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 °C for 72 hrs	Non-sensitizing
Systemic Toxicity **(ISO Acute Systemic Toxicity Test)**	Normal saline and sesame seed oil (SSO) (tested separately) Albino outbred strain (ND4) mice	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 °C for 72 hrs	Non-acute systemically toxic
Pyrogenicity **(ISO/USP Material Mediated Pyrogencity Test)**	Normal saline New Zealand White Rabbits	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 °C for 72 hrs	Non-pyrogenic

Test	Test Method Summary		Results
	Extract(s) & Test Systems	**Extract Conditions**	
Hemocompatibility **In-Vitro Blood Loop Assay** **(ISO In-vitro Blood Loop Assay with Comparison Article)**	A loop system circulated with freshly drawn sheep blood	The test article is exposed to the circulating blood that fills to the capacity of the loop at 37 °C for 4 hrs	Thromboresistant
Hemocompatibility Hemolysis Assay **(ISO ASTM Hemolysis Assay)**	PBS – Phosphate Buffered Saline Blood - Three New Zealand White Rabbits	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50 °C for 72 hrs	Non-hemolytic
Hemocompatibility **Complement Activation Assay** **(ISO Hemocompatibility: Complement Activation Assay (SC5b-9))**	Normal Human Serum (NHS)	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 37 °C for 60 min	Non-activator of complement system
Hemocompatibility **Partial Thromboplastin** **(ISO Hemocompatibility: Partial Thromboplastin Time (PTT) Assay)**	Human Plasma Freshly Drawn Human Plasma	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 37 °C for 15 min	No effect on the PTT

Test	Test Method Summary		Results
	Extract(s) & Test Systems	Extract Conditions	
Hemocompatibility **Heparinized Blood Platelet and Leukocyte** **(Hemocompatibility: Heparinized Blood Platelet and Leukocyte Count Assay)**	Human Blood Freshly Drawn Human Blood	12 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 37 °C for 60 min	Pass

Animal Study

Acute animal testing was conducted in accordance with FDA Good Laboratory Practice (GLP) Regulation (21 CFR Part 58) comparing the SOFIA 88 Catheter to the SOFIA 6F DAC. The testing was intended to assess preclinical safety and efficacy for catheter tracking and tip stability 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 tracking results demonstrated that the SOFIA 88 Catheter and SOFIA 6F DAC devices performed equally. Catheter tip stability was found to be comparable for both devices. No dissection/perforation was noted for the test-article- and control-treated vessels. Similar degrees of vasospasm were noted in the vessels instrumented with both devices. During postmortem examination there were no remarkable gross findings for any of the vessel samples for both the test and control devices. There was no hemorrhage, necrosis, or edema in test article-treated and control article-treated arterial sections. Overall, the histologic findings were consistent with routine catheterization procedures, which are commonly observed after interventional procedures in porcine safety models. The results of the present study did not raise any safety issues with either the test SOFIA 88 Catheter or control SOFIA 6F DAC. The devices are deemed equivalent.

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 SOFIA 88 Catheter is substantially equivalent to the predicate SOFIA 6F DAC. Any differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.