May 15, 2019

MicroVention, Inc.
Tina Ariaee
Sr. Manager, Regulatory Affairs
1311 Valencia Avenue
Tustin, California 92780

Re: K182602
Trade/Device Name: SOFIA® EX Intracranial Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 15, 2019
Received: April 16, 2019

Dear Tina Ariaee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Carlos L. Peña, PhD, MS
Director
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)*
K182602

Device Name
SOFIA® EX Intracranial Support Catheter

Indications for Use *(Describe)*
The SOFIA® EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA® EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA® EX 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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510(k) Summary

K182602

I. Submitter

MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780
Establishment Registration No: 2032493

Contact Person: Tina Ariaee
Senior Manager, Regulatory Affairs
Telephone: (714) 247-8000 Ext. 8366
Email: tina.ariaee@microvention.com

Date Prepared: May 12, 2019

II. Device

Name of Device	SOFIA® EX Intracranial Support Catheter
Common Name	Intracranial Support Catheter
Classification Name	Percutaneous Catheter (21 CFR 870.1250)
Regulatory Class	Class II
Product Code	DQY

III. Predicate Device

Predicate Device	SOFIA® Distal Access Catheter (K131482)
Reference Device	Navien Intracranial Support Catheter (K161152)

IV. Device Description

The SOFIA® EX Catheter is a single-lumen, flexible catheter equipped with the coil and the braid reinforcement. The distal segment is designed to facilitate vessel selection with 55-65cm of distal shaft hydrophilic coating for navigation through the vasculatures. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. The device is provided sterile and for single use. The catheter is placed in a dispenser tube (HDPE) and is placed on a packaging card (polyethylene) that is provided in a sterile barrier tyvek pouch and placed in a carton box.

V. Indications for Use

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

VI. Comparison of Technological Characteristics with the Predicate Device

	Medtronic Navien Intracranial Support Catheter (K161152)	SOFIA® Distal Access Catheter (K131482)	SOFIA® EX Catheter
	Reference Device	Predicate Device	Subject Device
Intended Use	The Navien Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The SOFIA® Distal Access Catheter is 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® EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA® EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA® EX Catheter is not intended for use in coronary arteries.
Device Classification	Class II DQY 21 CFR 870.1250	Class II DQY, DQO 21 CFR 870.1250 21 CFR 870.1200	Class II DQY 21 CFR 870.1250

	Medtronic Navien Intracranial Support Catheter (K161152)	SOFIA® Distal Access Catheter (K131482)	SOFIA® EX Catheter
	Reference Device	Predicate Device	Subject Device
Catheter Body	PTFE lined polymeric catheter, with hydrophilic coating and Nitinol Support.	Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer.	Outer layer of polyolefin elastomer, polyurethane elastomer (Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid, Nitinol coil, and PTFE.
Marker	Platinum	Platinum/Iridium	Same as SOFIA® DAC (K131482)
Hub		Nylon	Same as SOFIA® DAC (K131482)
Strain Relief		Polyurethane	Same as SOFIA® DAC (K131482)
Introducer		Pebax	Same as SOFIA® DAC (K131482)
Shaping Mandrel	none	Stainless steel	None
Catheter size	5F	5F	Same as SOFIA® DAC (K131482) and Navien (K161152)
ID	0.058 inch (1.5 mm)	0.055 inch (1.4 mm)	Same as Navien (K161152)
OD	0.070” Max.	0.068 inch (1.7 mm)	0.071 inch (1.8 mm)
Effective Length	105,115,125,130cm	115, 125 cm	105, 115 cm
Coating	Hydrophilic coating	Hydrophilic coating	Same as SOFIA® DAC (K131482)
Tip Construction and Material		Outer layer of polyurethane elastomer, inner layer of stainless steel braid (entire shaft)/stainless steel coil (except for distal 2cm), and polyolefin elastomer.	Outer layer of polyolefin elastomer, inner layer of stainless steel braid (except for distal 2cm)/ Nitinol coil (entire shaft), and PTFE.
Average Tip Stiffness (2cm length)	44 gf	16 gf	31gf

	Medtronic Navien Intracranial Support Catheter (K161152)	SOFIA® Distal Access Catheter (K131482)	SOFIA® EX Catheter
	Reference Device	Predicate Device	Subject Device
Guidewire Compatibility	0.038 inch	0.035 or 0.038 inch	Same as SOFIA® DAC (K131482)
Accessories	Introducer Sheath	Introducer sheath and shaping mandrel	Introducer sheath
Method of Supply	Sterile and single use	Sterile and single use	Same as SOFIA® DAC (K131482)
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same as SOFIA® DAC (K131482)
Packaging Configuration	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton.	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.	Same as SOFIA® DAC (K131482). No shaping mandrel.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench Study

Test	Test Method Summary	Results
Dimensional Inspection	The usable length, proximal and distal outer diameters, distal length and inner diameters were measured and recorded.	Device met acceptance criteria for length, inner and outer diameters. The device size (5F) comparable to the 5F predicate and reference devices. The inner diameter is larger than the predicate device, while the outer diameter is larger, but still compatible with tested 6F guiding sheaths.
Catheter Tip Stability	Simulated use of the delivery of a braided device is performed in a tortuous anatomical benchtop model and the movement of the subject device is measured and recorded.	Device met acceptance criteria for tip stability. The device is able to support the delivery of braided devices and stent-retrievers without losing distal tip position. The stability of the distal tip was better (less movement) than the predicate device.
Simulated Use and Physician Simulated Use	The device is put through simulated use. The device is navigated through a tortuous benchtop model to assess preparation, introduction, tracking, and support of the device.	Device met acceptance criteria
Dynamic Burst Testing	Device hub is connected to a pressure control machine and was tested under pressures experienced during worst-case dynamic injections.	Device met acceptance criteria and was able to withstand pressures experienced during worst-case dynamic injections.
Liquid Leakage	Device was tested per ISO 10555-1, Annex C liquid leakage testing. Device is connected at hub and is pressurized with fluid and maintains the pressure for a specified duration of time.	Device met acceptance criteria
Liquid Leakage at Rated Burst Pressure	Device was tested per ISO 10555-2 Annex A, liquid leakage testing. Device is connected at hub and is pressurized with fluid	Device met acceptance criteria and does not leak fluids at rated burst pressure.

	and maintains rated burst pressure for a specified duration of time.	
Air Leakage	Device was tested per ISO 594-2. Device is connected at hub and subjected to negative pressure and any air leaking into the device is recorded.	Device met acceptance criteria. Device does not allow air to leak into the device when subjected to negative pressure.
Static Burst	Device was connected at hub and tested under full-length static conditions to burst.	Device met acceptance criteria. All devices burst above the rated burst pressure and had better results than the predicate device.
Tensile Strength	Device was tested per ISO 11070. The device is tensile tested to failure and the force at break is measured and recorded.	Device met acceptance criteria.
Tip Buckling	Distal tip buckling force under compressive load was evaluated for stiffness.	Device met acceptance criteria. Device has a softer distal tip than the reference device.
Torque Response	Device was tested for full-length torque response. The device is tracked through a tortuous benchtop model and the proximal hub is turned, the distal tip torque response is measured and recorded.	Device met acceptance criteria. Device has better torque response than the reference device.
Radio-detectability	Device is put under fluoroscope to assess visibility.	Device met acceptance criteria. Device is visible under fluoroscopy.
Coating Lubricity and Durability	Device coating was evaluated for frictional force and durability.	Device met acceptance criteria. Average friction is comparable to predicate device.
Particulate Testing	Device was evaluated for particulate generation under simulated use in a representative tortuous anatomical model per USP<788>.	Number of particulates generated met acceptance criteria and is within the limits per USP<788> and is comparable to the predicate and reference devices.
Kink Resistance	Device is evaluated for kink resistance by subjecting the device to bending experienced in tortuous anatomy.	Device met acceptance criteria. Results matched results of the predicate device.
Corrosion Resistance	Device is tested per ISO 10555-1, Annex A and ISO 11070, Annex B to evaluate corrosion resistance.	Device met acceptance criteria. Device is resistant to corrosion.

Biocompatibility Study

Test	Test Method Summary		Results
	Extract(s) & Test Systems	Extract Conditions	
Cytotoxicity (ISO Medium Eluate Method (MEM) Elution Test)	1x CMEM Cell Growth Medium (MEM supplemented with 10% fetal bovine serum extract) L929 Mouse Fibroblast Cell Line	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 37°C/24 hrs.	Non-cytotoxic The test article is considered non-cytotoxic to cells.
Sensitization (ISO Kligman Maximization Test in Guinea Pigs Sensitization Test)	Normal Saline and Vegetable (Cottonseed) Oil Extracts Hartley Guinea Pigs	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50°C/72 hrs.	Non-sensitizing The test article did not elicit a sensitization response.
Irritation/ Intracutaneous Toxicity (ISO Intracutaneous Injection Test in Rabbits)	Normal Saline and Vegetable (Cottonseed) Oil Extracts	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50°C/72 hrs.	Non-irritant No evidence of irritation.
Systemic Toxicity (ISO Systemic Injection Test in Mice)	Normal Saline and Vegetable (Cottonseed) Oil Extracts Albino Swiss Mice	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50°C/72 hrs.	Non-cytotoxic No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice.
Systemic Toxicity (ISO Rabbit Pyrogen (Material-Mediated) Test)	Normal Saline New Zealand White Rabbits (2 Male and 2 Female – non-pregnant and nulliparous)	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), extracted at 50°C/72 hrs.	Non-pyrogenic All individual rabbits for both the test article and negative control showed a total rise in temperature of < 0.5ºC and were determined to be non-pyrogenic.
Hemocompatibility (ASTM Hemolysis Test - Rabbit Blood – Direct and Indirect Contact Methods)	Direct Contact Solid Sample Exposure to Rabbit Blood Substrate and Indirect Contact Extracted in Phosphate Buffered Saline (PBS) New Zealand White Rabbits	Both Direct and Indirect Contact Methods Direct Contact: 6.0 cm^2/mL (exposed surface area to extraction medium volume ratio), exposure to Blood Substrate then	Non-hemolytic There were no significant differences between the test article extract/solid and negative control article results.

		Incubated at 37ºC for 3 hours. Indirect Contact: 6.0 cm2/mL (exposed surface area to extraction medium volume ratio) in PBS. Extracted at 50°C for 72 hours then Extract Exposed to Blood Substrate and Incubated at 37ºC for 3 hours.	
Hemocompatibility (ISO Unactivated Partial Thrombinplastin Time (UPTT) Test – Direct Contact Method)	Solid Sample Exposure to Human Plasma	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio). Incubated with human plasma at 37ºC for 15 minutes.	No adverse effect on Unactivated Partial Thrombinplastin Time of human plasma The solid test article was determined to be compatible with blood and not affect coagulation.
Hemocompatibility (ISO Complement Activation (C3 and SC5b-9) Test – Direct Contact)	Solid Sample and Normal Saline Extract then Exposure to Human Plasma	Direct Contact: 6.0 cm^2/mL (exposed surface area to extraction medium volume ratio). Exposure to Human Plasma then Incubated at 37ºC for 90 Minutes.	C3a and SC5b-9 complement proteins were considered to be non-activated as compared to the negative control
Hemo-compatibility (ISO In Vitro Hemocompatibility Test – Direct Contact Method)	Solid Sample Exposure to Human Plasma	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio). Incubated with human plasma at 37ºC for 60 minutes.	Hemocompatible The test article was determined to be hemocompatible with direct exposure to human blood for the blood parameters (WBC, RBC, HgB, Hct, MCV, MCH, MCHC, and Plt).
Hemo-compatibility (Large Animal Thrombogenicity Test)	Final Devices Used in a Simulated Clinical Application tested on Female Yorkshire pigs	Direct Exposure	Non-thrombogenic. No significant thrombus was observed on any of the SOFIA® EX Catheter devices and the device was determined to not show thrombogenic potential.

Genotoxicity – Gene Mutation (ISO In Vitro Ames Test – Salmonella typhimurium and Escherichia coli Reverse Mutation Genotoxicity Test)	Normal Saline and Vegetable (Cottonseed) Oil Extracts Salmonella. typhimurium TA98, TA100, TA1535, TA1537, and E. coli WP2 uvr A under both Non-Activated and Activated Systems	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio). Extracted at 50°C/72 hrs.	Non-mutagenic Based on the acceptance criteria under the experimental conditions utilized, the test article extracts were both deemed non-mutagenic in all strains under both non-activated and activated conditions.
Genotoxicity – Chromosomal Aberration (In Vitro Chromosomal Aberration Genotoxicity Test)	Ham's F12 Cell Growth Medium and PEG 400 Chinese Hamster Ovary (CHO) Cells under both Non-Activated and Activated Systems	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio). Extracted at 50°C/72 hrs.	Non-mutagenic Based on the criteria of the study protocol, the test article was considered to be non-mutagenic.
Genotoxicity – Chromosomal Aberration (In Vivo Rodent Blood Micronucleus Genotoxicity Test)	Normal Saline and Vegetable (Cottonseed) Oil Albino Swiss Mice	6.0 cm^2/mL (exposed surface area to extraction medium volume ratio). Extracted at 50°C/72 hrs.	Non-mutagenic Based on the criteria of the study protocol, the test article was considered to be non-mutagenic.

Animal Study

An acute animal testing was conducted in accordance with FDA GLP Regulation (21 CFR Part 58) comparing the SOFIA® EX Catheter to the Medtronic Navien Intracranial Support Catheter. The testing was intended to demonstrate clinical efficacy for catheter tip stability and safety in a porcine model. Three female Yorkshire pigs were chosen given the vessel sizes of the pig model allow for insertion and navigation of standard-sized devices used in humans and have diameters that are comparable with that of the human peripheral vasculature. The tracking results demonstrated that the SOFIA® EX and Navien devices performed equally in tracking over the microcatheter/guidewire. No dissection/perforation, thrombus formation or distal emboli were noted after the tracking procedures. Similar degrees of vasospasm and luminal narrowing were noted in the vessels instrumented with both devices. During explant there were no remarkable gross findings for any of the vessel samples for both the candidate and reference devices. All vessels appeared intact with no visible wall disruptions, ectasia, or aneurysmal dilation. Overall, the histologic findings were consistent with routine catheterization procedures, which are commonly observed with guide wires alone in the porcine safety models. The results of the present study did not raise any safety issues with either the control Navien or test SOFIA® EX catheter. Both devices are deemed equivalent.

VIII. Conclusions

MicroVention concludes through a review of the benchtop and non-clinical animal assessments, the comparison of the device classification, indications for use, operating principle, technological characteristics, sterility and biocompatibility that the SOFIA® EX Catheter is substantially equivalent to the predicate SOFIA® Distal Access Catheter and the reference device Navien Intracranial Support Catheter. Any differences between the subject device and the predicate and reference device do not raise different questions of safety and effectiveness.