September 14, 2023

MicroVention, Inc.
Miranda Beach
Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K230775
Trade/Device Name: SOFIA EX Intracranial Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: August 15, 2023
Received: August 16, 2023

Dear Miranda Beach:

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,
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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)*
K230775

Device Name
SOFIA EX Intracranial Support Catheter

Indications for Use *(Describe)*
The SOFIA EX Intracranial Support Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Intracranial Support Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Intracranial Support 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 K230775

510(k) Owner	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 Establishment Registration No: 3013556777
Contact Person	Miranda Beach Regulatory Affairs Specialist Email: Miranda.Beach@microvention.com
Date of Preparation	September 12, 2023
Trade Name	SOFIA™ EX Intracranial Support Catheter
Common Name	Catheter, Percutaneous, Neurovasculature
Classification	Class II, QJP, DQY
Regulation	21 CFR 870.1250
Predicate Device	SOFIA EX Intracranial Support Catheter (K182602)
Reference Device	Benchmark Intracranial Access System (K212838)

Device Description

The SOFIA™ EX Intracranial Support Catheter is a single-lumen, flexible catheter equipped with coil and braid reinforcement. The distal segment is designed to facilitate vessel selection with 55-65cm 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. 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.

Indications for Use

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

Comparison of Indications for Use and Technological Characteristics

The subject device is identical in its indication for use, technology, principle of operation, materials, sterilization method, and performance to the predicate device SOFIA™ EX Intracranial Support Catheter (K182602). The only difference between the subject and predicate devices are additional instructions added to the instructions for use (IFU) for the subject device

related to radial access use. A comparison of the technological characteristics of the subject device and the predicate device is summarized in Table 1 below.

Table 1: Technological Characteristics Comparison

	SOFIA™ EX Intracranial Support Catheter (K182602)	**SOFIA™ EX Intracranial Support Catheter**
	Predicate Device	**Subject Device**
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.	The SOFIA EX Intracranial Support Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Intracranial Support Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Intracranial Support Catheter is not intended for use in coronary arteries.
Device Classification	Class II DQY 21 CFR 870.1250	Class II QJP, DQY 21 CFR 870.1250
Catheter Body Materials	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.	Same
Marker	Platinum/Iridium	Same
Hub	Nylon	Same
Strain Relief	Polyurethane	Same
Introducer	Pebax	Same
Catheter Size	5F	Same
Inner Diameter (ID)	0.058 in.	Same

	SOFIA™ EX Intracranial Support Catheter (K182602)	SOFIA™ EX Intracranial Support Catheter
	Predicate Device	**Subject Device**
Outer Diameter (OD)	0.071 in.	Same
Effective Length	105 cm, 115 cm.	115 cm.
Coating	Hydrophilic Coating	Same
Tip Configuration	Straight	Same
Guidewire Compatibility	≤ 0.038 in. OD	Same
Accessories	Introducer Sheath	Same
Method of Supply	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide	Same
Packaging Configuration	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.	Same

Performance Testing

The following bench testing data were provided to evaluate the performance and support the substantial equivalence of the SOFIA™ EX Intracranial Support Catheter.

Test	Test Method Summary	Results
Simulated Use and Physician Simulated Use	The simulated use of the device is evaluated in a tortuous anatomical benchtop model to assess tracking and hydrophilic coating lubricity of the device. Physician simulated use is conducted with subject the	Device met acceptance criteria.

	device to provide comparison with the reference device.	
Kink Resistance	Device is subjected to bending experienced in tortuous anatomy.	Device met acceptance criteria.
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.	Number of particulates generated are comparable to the predicate device.

Biocompatibility

The subject device, SOFIA™ EX Intracranial Support Catheter is categorized as a limited exposure (≤ 24 hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1. The design and manufacturing of the subject device, SOFIA™ EX Intracranial Support Catheter use identical materials, processing, and sterilization method as the predicate device, SOFIA™ EX Intracranial Support Catheter (K182602) for which MicroVention has already successfully conducted biocompatibility testing per ISO 10993-1. Therefore, no additional biocompatibility testing is required.

Performance Data – Animal, Clinical

No animal or clinical studies were conducted because bench testing was determined sufficient for verification and validation purposes.

Conclusions

The subject SOFIA™ EX Intracranial Support Catheter is substantially equivalent to the predicate device SOFIA™ EX Intracranial Support Catheter. The subject device has the same indications for use as the predicate device. The 510(k) Summary demonstrates that the subject device is substantially equivalent to the predicate device regarding operating principle, design, fundamental technology, and the device performs as intended. The changes to the instructions for use do not raise new questions of safety and effectiveness.