June 11, 2018

MicroVention, Inc.
Naomi Gong
Associate Director, Regulatory Affairs
1311 Valencia Avenue
Tustin, California 92780

Re: K173200
Trade/Device Name: SOFIA Plus Aspiration Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 27, 2018
Received: May 1, 2018

Dear Naomi Gong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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,

Xiaolin Zheng -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K173200

Device Name
SOFIA Plus Aspiration Catheter

Indications for Use *(Describe)*
The SOFIA Plus Aspiration Catheter with the Gomco 405 Aspiration Pump and MicroVention Tubing Kit is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

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.

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510(k) Summary – K173200

Pursuant to Section 12, Part (a)(i)(3)(A) of the Safe Medical Devices Act of 1990, MicroVention, Inc. is providing this summary of substantial equivalence for the SOFIA™ Plus Aspiration Catheter (21 CFR 807.92).

Applicant Name and Address

MicroVention, Inc.
1311 Valencia Avenue
Tustin, California 92780 USA

Contact Information

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Date of Preparation of the 510(k) Summary

June 5, 2018

Device Trade or Proprietary Name

SOFIA Plus Aspiration Catheter

Device Classification

Regulatory Class:	II
Classification Panel:	Neurology
Regulation Name(s):	Percutaneous Catheter
Regulation Number(s):	21 CFR 870.1250
Product Code:	NRY (Catheter, Thrombus Retriever)

Predicate Device

Penumbra Reperfusion Catheter ACE64 and ACE68 (K152541)

Indications for Use

The SOFIA Plus Aspiration Catheter with the Gomco 405 Aspiration Pump and MicroVention Tubing Kit is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Device Description

The SOFIA Plus Aspiration Catheter is a single lumen catheter designed to be introduced over a steerable guidewire to access the neurovasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. A single radiopaque marker at the distal end facilitates fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic coating to reduce friction during navigation in the vasculature. A luer fitting on the microcatheter hub is used for the attachment of accessories. The strain relief at the hub provides kink resistance for the proximal end. A steam shaping mandrel and introducer sheath are also packaged with the catheter. The SOFIA Plus Aspiration Catheter is used to remove thrombus/embolus from the neurovasculature using aspiration tubing and pump.

Technological Characteristics Comparison Table

	Penumbra Reperfusion Catheter ACE 64/68 (K152541 predicate device)		**SOFIA Plus Aspiration Catheter** (subject device)
Indication	The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.		SAME: The SOFIA Plus Aspiration Catheter with the Gomco 405 Aspiration Pump and MicroVention Tubing Kit is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Material Catheter body	Outer layer of polyurethane elastomer (Tecoflex and Pellethane), polyether block amide (Pebax) and polyamide (Vestimid); inner layer of stainless steel and/or NiTi coil		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
Marker band	Pt/Ir		Pt/Ir
Hub	Nylon (Grilamid)		Nylon
Strain relief	Nylon (Grilamid)/SS304		Polyurethane
Introducer	PTFE		Pebax
Shaping mandrel	Stainless Steel		Stainless steel
ID	ACE64: Prox = 0.068 in. Min Distal = 0.064 in. Min	ACE68: 0.068 in. Min	0.070 in.
OD	ACE64: Prox = 0.084 in. Max Distal = 0.080 in. Max	ACE68: 0.084 in. Max	Prox: 0.083 in. Distal: 0.082 in.
Effective Length	115 – 132 cm		125 - 131 cm
Coating	Hydrophilic coating (SRDX Harmony)		Hydrophilic coating (Hydak®)
Tip Configuration	Steam shapeable by user		Steam shapeable by user
Accessories	Peelable sheath, rotating hemostatic valve, shaping mandrel		Introducer sheath and shaping mandrel
Method of Supply	Sterile and single use		Sterile and single use
Sterilization Method	Ethylene oxide		Ethylene oxide
Packaging Configuration	Polyester/polyethylene/Tyvek® pouch, Polyethylene hoop, polyethylene card, paperboard carton.		Polyester/polyethylene/Tyvek® pouch, Polyethylene tube, polyethylene card, paperboard carton.
Components			
Aspiration Pump	Penumbra Aspiration Pump Vacuum of -25 in Hg		Gomco 405 Aspiration Pump Same
Aspiration Tubing	112 inch length Tubing ID = 0.110 inch Integrated valve for vacuum control		Same

Summary of Pre-Clinical Testing

Included in this section are summary descriptions of the non-clinical testing which substantiates the performance of the subject device, the SOFIA Plus Aspiration Catheter:

Biocompatibility Testing:

Biocompatibility	Results	Conclusions
Cytotoxcitiy (ISO 10993-5) - MEM elution assay	Cell culture treated with test article exhibited slight reactivity (Grade 1)	Non-cytotoxic PASSED
Sensitization/Irritation (ISO 10993-10) - Guinea pig maximization sensitization	Extracts of the test article elicited no reaction at the challenge (0% sensitization) following the induction phase (Grade 1).	Weak allergic potential or sensitizing capacity PASSED
Sensitization/Irritation (ISO 10993-10) - Intracutaneous reactivity	Extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control article	Non-irritant PASSED
Hemocompatibility – Rabbit Blood Direct and Indirect Contact (ISO 10993-4)	The hemolysis index was 0.13% (direct contact) and 0.0% (indirect contact)	Non-hemolytic PASSED
Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO 10993-4)	No statistically significant difference found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control	No effect on coagulation PASSED
Hemocompatibility – Complement Activation Assay (ISO 10993-4)	C3a and SC5b-9 levels $\leq$ negative and untreated controls	No effect on complement activation PASSED
Hemocompatibility – Thrombogenicity Study in Dogs (ISO 10993-4)	Minimal thrombosis observed with a Grade 0 in two out of two test sites and two out of two control sites	No significant thrombosis PASSED
Systemic Toxicity – Systemic Injection Test (ISO 10993-11)	Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected in Swiss Albino mice	No toxic effects PASSED
Systemic Toxicity - Rabbit Pyrogen Test (ISO 10993-11)	The temperature increases (maximum) was 0.03^{o}C from baseline	Non-pyrogenic PASSED

Verification and Test Summary:

The physical and mechanical properties of the SOFIA Plus Aspiration Catheter device were assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Bench Testing		
Test	**Results**	**Conclusions**
Simulated Use	Test articles achieved a rating $\geq$ 3 for preparation/ease of assembly, introducer sheath interaction, introducer peel away, tracking with guidewire/microcatheter, microcatheter/guidewire lockup, lubricity and durability of hydrophilic coating, microcatheter/ guidewire removal, removal/ aspiration of clot.	Device performs as intended and demonstrates equivalency to its predicate devices under simulated use conditions
Dimensional and Physical Attributes	Test articles met the specified dimensional requirements for catheter OD, catheter ID,	Device met established dimensional and physical

Bench Testing		
Test	**Results**	**Conclusions**
	overall working length, length of distal section, length of distal tip to marker band and total length of hub/strain relief	specifications and is substantially equivalent to the predicate device
Kink Resistance	No kinks when wrapped around 0.030 and 0.040-inch pin gauges No kinks noted during simulated use testing	Device resistant to kinking around small radii turns Same as predicate device
Durability/Lubricity of Hydrophilic Coating	Test article achieved a rating of ≥ 3 during simulated use testing for coating durability and lubricity.	Device tracks easily with no coating cracking or separation
Catheter Stiffness	Device stiffness equivalent to predicate and competitive devices	Device tracks in tortuous anatomy while advancing to target site
Catheter Flexural Fatigue	No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing	Device integrity suitable for intended clinical use
Force at Break (Shaft and hub)	Catheter force at break ≥ 15N for shaft section and hub/catheter junction	Tensile strength test results meet acceptance criteria and equivalent to predicate and competitive devices
Force at Break (After tip shaping)	Catheter force at break ≥ 15N for distal section assessed pre- and post-tip shaping	Device meets acceptance criteria and no difference between pre- and post- force at break
Static Burst Pressure	No damage of pressurized catheter at 46 psi	Device integrity suitable for intended clinical use and met requirements of ISO 10555-1
Fluid Leakage at > 46 psi	No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds	Device integrity suitable for intended clinical use and met requirements of ISO 10555-1
Air Leakage	No air leakage at hub into syringe for 15 seconds	Device integrity suitable for intended clinical use and met requirements of ISO 10555-1
Dynamic Burst	Test articles did not burst at or below 300 psi	Device met labeled maximum infusion pressure of 300 psi
Catheter Collapse	Test articles were pressurized for a duration of 6 minutes and no observation of catheter collapse	No observation of device collapse, equivalent to predicate device
Vacuum Pressure	Vacuum pressure testing of catheter at distal tip was compared to vacuum pressure of source. No difference detected.	No difference was measured between device and predicate
Torque Response	Catheter torque response was assessed in vascular model and met acceptance criteria.	Equivalent or better than predicate
Torque Strength	Catheter was torqued and did not break	Met acceptance criteria
Advance/Retract	Catheter was subjected to advance/retraction test in a vascular model and was equivalent or better than predicate	Met acceptance criteria
Radiopacity	Marker band was detectable under fluoroscopy	Marker band is visible under fluoroscopy
Corrosion Resistance	Met ISO 10555-1	Catheter is corrosion resistant
Particulate Testing	Met USP <788> criteria	Catheter does not generate particulate.

Animal Study:
The SOFIA Plus Aspiration Catheter was evaluated in a comparative animal study that was conducted to evaluate its aspiration performance and its safe use in a swine model. Histopathological evaluations of the affected vasculature using the device were also performed as part of the study.

Summary of Clinical Data:
Not applicable

Summary of Substantial Equivalence

The data presented in this submission demonstrate the technological similarity and performance equivalency of the SOFIA Plus Aspiration Catheter when compared with the predicate device, the Penumbra Reperfusion Catheter ACE 64 and ACE 68 (K152541).

The devices:

- Have the same intended use and indications for use,
- Have the same mode of action,
- Use the same operating principle,
- Incorporate the same basic design, materials, dimensional and physical characteristics, and
- Are packaged and sterilized using same methods, with similar shelf-life.

In summary, the SOFIA Plus Aspiration Catheter described in this submission is substantially equivalent to its predicate device, Penumbra Reperfusion Catheter ACE 64 and ACE 68 (K152541).