July 10, 2019

MicroVention, Inc.
Marina Emond
Senior Manager, Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K182829
Device Name: Scepter Mini Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN, DQY
Dated: June 7, 2019
Received: June 10, 2019

Dear Marina Emond:

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,

Xiaolin Zheng, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182829

Device Name
Scepter Mini Occlusion Balloon Catheter

Indications for Use *(Describe)*
The Scepter Mini Occlusion Balloon Catheter is intended:

For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms.

For use in the peripheral vasculature for the delivery of diagnostic agents, such as contrast media, that have been approved or cleared for use in the peripheral vasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.

For neurovascular use for the delivery of diagnostic agents, such as contrast media, and liquid embolic agents that have been approved or cleared for use in the neurovasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.

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

Trade Name:	Scepter Mini Occlusion Balloon Catheter
Generic Name:	Percutaneous Catheter
Classification:	Class II, 21 CFR 870.4450 (MJN) and 21 CFR 870.1250 (DQY)
Submitted By:	MicroVention, Inc. 35 Enterprise Aliso Viejo, California 92656, USA
Contact:	Marina Emond Senior Manager, Regulatory Affairs Marina.Emond@Microvention.com (714) 247-8296
Date:	October 4, 2018
Predicate Device:	Scepter C Occlusion Balloon Catheter (K110741, K121785) Scepter XC Occlusion Balloon Catheter (K113698, K121785)
Reference Device:	Headway 17 Microcatheter (K083343)

Device Description:

Scepter Mini Occlusion Balloon Catheter is a dual co-axial lumen balloon catheter. The catheter is designed to track over a steerable guidewire. The outer lumen is used for the inflation and deflation of the balloon independent of guidewire position. The inner lumen can be used to deliver diagnostic agents or liquid embolics to distal locations in tortuous anatomy. Radiopaque marker bands are located at each end of the balloon to facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories. The catheter is packaged sterile for single use only.

The Scepter Mini has similar indications for use as the predicates, however, incorporates several minor design differences. The Scepter Mini has a slightly longer length and a slightly smaller diameter. The balloon of the

Scepter Mini is slightly shorter. The distal tip of the Scepter Mini extends a shorter distance from the distal end of the balloon than that of the Scepter C and XC. For the Scepter Mini, the purge hole is covered by a semi-permeable membrane designed to allow air to escape while preventing liquids from passing. The predicate Scepter C and XC incorporate 3 radiopaque marker bands, while the design of the Scepter Mini allows for visualization under fluoroscopy with only 2 radiopaque marker bands (due to shorter distal tip segment). All Scepter catheters have a hydrophilic coating.

Indications for Use:

The Scepter Mini Occlusion Balloon Catheter is intended:

For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms.

For use in the peripheral vasculature for the delivery of diagnostic agents, such as contrast media, that have been approved or cleared for use in the peripheral vasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.

For neurovascular use for the delivery of diagnostic agents, such as contrast media, and liquid embolic agents that have been approved or cleared for use in the neurovasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.

Technological Characteristics and Product Feature Comparison:

The subject device, Scepter Mini Occlusion Balloon Catheter, is substantially equivalent to the predicate devices in terms of:

- Intended use
- Scientific technology
- Fundamental design
- Materials and processes for packaging and sterilization of devices

A tabular comparison of the technological characteristics between the predicate devices and subject device is provided below.

Technological Characteristics Comparison of Subject Device with Predicate Device

Device Characteristics	Scepter C Occlusion Balloon Catheter (K110741, K121785)	Scepter XC Occlusion Balloon Catheter (K113698, K121785)	Scepter Mini Occlusion Balloon Catheter (Subject Device)
Device Classification/ Product Code	Class II/ DQY (Percutaneous catheters)	Class II/ DQY (Percutaneous catheters)	Class II/ DQY (Percutaneous catheters)
Intended Use	Intended for use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms. Intended for use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. It is intended for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC Occlusion Balloon Catheters.		Similar Intended Use For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheter provides temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheter also offers balloon assisted embolization of intracranial aneurysms. For use in the peripheral vasculature for the delivery of diagnostic agents, such as contrast media, that have been approved or cleared for use in the peripheral vasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter. For neurovascular use for the delivery of diagnostic agents, such as contrast media, and liquid embolic agents that have been approved or cleared for use in the neurovasculature and are compatible with the inner lumen of the Scepter Mini Occlusion Balloon Catheter.
Catheter OD	Proximal = 2.8 Fr Distal = 2.6 Fr	Proximal = 2.8 Fr Distal = 2.6 Fr	Proximal = 2.8 Fr Distal = 1.6 Fr

Device Characteristics	Scepter C Occlusion Balloon Catheter (K110741, K121785)	Scepter XC Occlusion Balloon Catheter (K113698, K121785)	Scepter Mini Occlusion Balloon Catheter (Subject Device)
Inner Lumen Diameter (Distal to Proximal)	0.0165" (0.419 mm) Un-tapered inner lumen	0.0165" (0.419 mm) Un-tapered inner lumen	0.0100" - 0.0155" (0.254 mm - 0.394 mm) Tapered inner lumen The Scepter Mini's inner lumen incorporates a taper in order to achieve a 1.6F distal OD, while the inner lumen of Scepter C and XC is straight.
Lumen configuration	Dual coaxial lumen	Dual coaxial lumen	Same
Balloon Type	Compliant, Polyurethane Elastomeric	Extra Compliant, Polyurethane Elastomeric	Compliant, Polyurethane Elastomeric
Balloon Diameter	4 mm	4 mm	2.2 mm
Balloon Length	10, 15, 20 mm	11 mm	9 mm
Working Length	150 cm	150 cm	165 cm
Radiopaque Marker Bands	3	3	2 The predicate Scepter C and XC incorporate 3 radiopaque marker bands, while the Scepter Mini allows for visualization under fluoroscopy with 2 radiopaque marker bands (due to the shorter distal tip segment).
Air Purge	Purge hole	Purge hole	The air purge hole is covered by a semi-permeable membrane designed to allow the removal of air from the balloon while preventing escape of inflation liquids.
Shaping Mandrel	Included in single catheter package	Included in single catheter package	None The Scepter Mini distal tip is not shapeable therefore no shaping mandrel is provided.
Introducer sheath	Included in single catheter package	Included in single catheter package	Same
Guidewire Compatibility	0.014" wire or smaller	0.014" wire or smaller	0.008" or smaller

Device Characteristics	Scepter C Occlusion Balloon Catheter (K110741, K121785)	Scepter XC Occlusion Balloon Catheter (K113698, K121785)	Scepter Mini Occlusion Balloon Catheter (Subject Device)
Coating	Hydrophilic Coating	Hydrophilic Coating	Same
Hub	2 port design	2 port design	Same
Strain Relief	Dynaflex material	Dynaflex material	Pebax material
Packaging Material	Dispenser hoop: Polyethylene Mounting card: Polyethylene Pouch: Tyvek Carton Box: Bleached Sulfate		Same packaging with an additional stylet inserted in the guide wire lumen for support of the catheter while being inserted in the packaging hoop. The stylet is removed and disposed of before use of the catheter.
Package Configuration	Microcatheter is placed in a dispenser hoop and accessories on a mounting card that is then inserted into the pouch. The pouch is then placed inside a carton box.		
Method of Supplying	Sterile and single use	Sterile and single use	Same
Method of Sterilization	Ethylene oxide	Ethylene oxide	Same

Verification Test Summary:

The results of verification and validation testing conducted on the subject device demonstrate that it performs as intended and are summarized as follows:

Test Description	Result
Sterility	Subject device is processed under the same sterilization method (Ethylene Oxide) and meets the same sterility assurance level (SAL 10^{-6}) as predicates Scepter C/XC (K121785). Validation of the EtO sterilization method for Scepter Mini was conducted in accordance with requirements of ISO 11135-1, using the overkill method. The EtO and ECH residual levels were 0.2 mg per device respectively, meeting the residual level requirements per ISO 10993-7. The bacterial endotoxin test results were <0.01 EU/mL meeting the specification of <0.06 EU/mL (<2.15 EU/Device) per USP <161>
Physical Attributes	Pass Physical dimensions of subject device meet design specifications.
Force at break	Pass Subject device does not break during use and meets same specification for force at break as predicates Scepter C/XC (K121785).
Freedom from Leakage – Fluids (low pressure, long duration)	Pass Subject device does not leak fluids at low pressure/long duration and meets same specification for freedom from leakage as predicates Scepter C/XC (K121785).
Freedom from Leakage – Air	Pass Air does not leak into subject device meeting same specification as predicates Scepter C/XC (K121785).
Freedom from Leakage – Liquid (high pressure, short time)	Pass Subject device does not leak fluids at high pressure/short duration and meets same specification for freedom from leakage as predicates Scepter C/XC (K121785).

Test Description	Result
Burst Pressure of Catheter	Pass Subject device does not burst statically below rated burst pressure meeting same specification as predicates Scepter C/XC (K121785).
Gauging Test	Pass Catheter luer compatible to other standard luer fittings. Data leveraged from predicate Scepter C (K110741, K121785) due to the same hub design.
Separation Force	Pass Catheter luer compatible to other standard luer fittings. Data leveraged from predicate Scepter C (K110741, K121785) due to the same hub design.
Unscrewing Torque	Pass Catheter luer compatible to other standard luer fittings. Data leveraged from predicate Scepter C (K110741, K121785) due to the same hub design.
Ease of Assembly	Pass Subject device luer mates together with other compatible fittings.
Resistance to Overriding	Pass Catheter luer mates with other compatible fittings. Data leveraged from predicate Scepter C (K110741, K121785) due to the same hub design.
Stress Cracking	Pass Catheter hub does not leak. Data leveraged from predicate Scepter C (K110741, K121785) due to the same hub design.
Durability of Hydrophilic Coating	Pass Hydrophilic coating does not flake off during use, is of the same material and meets same specification as predicates Scepter C/XC (K121785).

Test Description	Result
Lubricity of Hydrophilic Coating	Pass Hydrophilic coating is lubricious, of the same material and meets same specification as predicates Scepter C/XC (K121785).
Simulated Use	Pass Subject device demonstrated equivalent performance during simulated use with similar ratings to predicates Scepter C/XC (K121785).
Compatibility with device/agents: Embolic material, contrast media, dimethyl sulfoxide (DMSO).	Pass Subject device is compatible with embolic material, contrast media, and DMSO, meeting same specification as predicates Scepter C/XC (K121785).
Dynamic Burst Pressure	Pass Subject device does not burst dynamically below rated burst pressure and meets same specification as predicates Scepter C/XC (K121785).
Radio-Detectability	Pass Radiopaque marker bands are visualized under fluoroscopy.
Kink resistance	Pass Subject device does not kink during normal use meeting same specification as predicates Scepter C/XC.
Non-pyrogenic	Pass Subject device bacterial endotoxins level is less than 2.15 EU/device.
Simulated Shipping and Packaging Testing	Pass Subject device showed no defects that compromise integrity of package, met seal strength, creep to burst, and dye penetration specification.
Catheter Flexural Fatigue	Pass Subject device met same specification as predicates Scepter C/XC (K121785) for flexural fatigue, pressure integrity, and hoop stress.

Test Description	Result
In Vivo Testing • In vivo performance characteristics • Histopathology evaluation	Pass Data from the predicate device Scepter C (K110741) used to support safety and performance of the subject device due to its larger OD profile, higher stiffness and trackability force.
Balloon Rated Burst Volume	Pass Balloon does not burst during use meeting same specification as predicates Scepter C/XC (K121785).
Balloon Compliance (rated volume)	Pass Balloon consistently inflates to the desired OD meeting same specification as predicates Scepter C/XC (K121785).
Balloon Inflation/Deflation Times	Pass Balloon inflates and deflates within an acceptable time range meeting same specification as predicates Scepter C/XC (K121785).
Balloon Fatigue Test	Pass Balloon does not burst before acceptable minimum cycle(s) meeting same specification as predicates Scepter C/XC (K121785).
Torque Test	Pass Subject device maintains acceptable torque during use meeting same specification as predicates Scepter C/XC (K121785).
Packaging and Shelf Life	Pass Sterile barrier is maintained during shelf life of product.
Insertion tool performance: Ease to enter RHV.	Pass Ease to enter RHV rated 3 or higher in tested category meeting same specification as predicates Scepter C/XC (K121785).
Decay Test	Pass Balloon maintains rated burst OD for a minimum of 30 min meeting same specification as predicates Scepter C/XC (K121785).

Test Description	Result
Surface Contamination	Pass Subject device samples were inspected for surface contamination for uncured coating, particulate greater than 0.02 mm^2, sharp edges, and embedded particulate. All samples passed the acceptance criteria of No Contamination.
Corrosion Resistance	Pass Metallic components show no signs of corrosion. Data leveraged from reference device Headway 17 (K083343) as the metal components are of the same material.
Catheter Particle Testing	Pass Subject device demonstrated less than 25 particles greater than 10 microns and less than 3 particles greater than 25 microns per 1mL meeting same specification as predicates Scepter C/XC (K121785).

Animal Testing Summary:

Evaluation of the in-vivo performance characteristics of the MicroVention Scepter balloon catheters was performed using the predicate device Scepter C in an acute swine animal model compared with a commercially equivalent device. There were no significant differences between the Scepter C balloon catheter and the control catheter in categories of performance and histopathologic evaluation. There was no denudation, perforation, dissection, or clinically significant injury to the target vasculature where the test device and the control device maneuvered through the swine anatomy. The Scepter C is considered the worst case for the Scepter Balloon Catheters in terms of in-vivo performance characteristics due to its larger OD profile, higher stiffness and trackability force. The proposed Scepter Mini device has smaller outer diameter profile and, based on the stiffness data, is softer, easier to track, and is less traumatic to the vessel. Therefore, the animal study results were leveraged from the predicate device.

Biocompatibility Evaluation:

The in vitro and in vivo biocompatibility safety studies performed on the Scepter Mini Occlusion Balloon Catheter have demonstrated the biocompatibility of the proposed device and support compliance with the ISO 10993-1:2009 and FDA guidelines. The device was determined to be non-sensitizing, intracutaneously non-irritating, systemically non-toxic, non-pyrogenic (material-mediated),

non-hemolytic, non-complement activating, non-mutagenic, have no effect on clotting and hematological parameters, and have no clastogenic effect. The results of biocompatibility evaluation are summarized as follows:

Test	Test Summary	Conclusions
Cytotoxicity - Medium Eluate Method	The test article extract exhibited between no cell lysis (grade 0) to slight reactivity (grade 1).	Non-cytotoxic
Sensitization: Maximization Test in Guinea Pigs	No irritation was present on any of the test or negative control (0% sensitized) guinea pigs.	Non-sensitizer
Intracutaneous Reactivity	No evidence of irritation (score 0.0).	Non-irritating
Systemic Injection Test in Mice	No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice was observed.	Systemically non-toxic
Rabbit Pyrogen Test	The rise of rabbit temperatures during the three hours of observation did not exceed 0.5 ºC.	Nonpyrogenic
ASTM Blood Compatibility - Direct and Indirect Contact Hemolysis	The test article demonstrated 0.59% hemolysis in direct contact and 1.25% hemolysis in indirect contact.	Non-hemolytic
Unactivated Partial Thromboplastin Time Test	An average clotting time of the test article showed no significant difference from the control.	No effect on clotting
Complement Activation	The plasma exposed to the test article for 90 minutes was found to exhibit no statistically significant increase in SC5b-9.	Non-activated
In Vitro Hemocompatibility Test -Human Blood, Direct Contact	The concentration of White Blood Cells (WBC) and Platelets in human blood exposed to the test article was not statistically significantly decreased.	No effect on hematological parameters
Salmonella thypimurium and *Escherichia coli* Reverse Mutation Assay	The test article extracts did not induce a statistically significant increase in the number of revertant colonies.	Non-mutagenic
Mouse Lymphoma Mutagenesis Assay	The increased mutant frequency (IMF) of the cells exposed to the test article extracts was less than the Global Evaluation Factor (GEF) 126 x 10^{-6}.	Non-mutagenic
Rodent Blood Micronucleus Assay	The test article did not result in a statistically significant increase in the percentage of reticulocytes containing micronuclei.	No clastogenic effect

Summary of Substantial Equivalence:

The information presented in this 510(k) demonstrates the substantial equivalence between the predicates and the Scepter Mini Occlusion Balloon Catheter with regard to the design, construction materials, operating principle and intended use.