April 27, 2023

MicroVention, Inc.
Sapna Singh
Director, Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K222694
Trade/Device Name: EmPro EPS™ (EP4514C-190, EP6514C-190);
Nanoparasol™ EPS (PNP4514C-190,PNP6514C-190)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: March 27, 2023
Received: March 28, 2023

Dear Ms. Singh:

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2023.04.27 14:30:34 -04'00'

For
Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K222694

Device Name
EmPro™ EPS (EP4514C-190 and EP6514C-190);
Nanoparasol™ EPS (NP4514C-190 and NP6514C-190)

Indications for Use *(Describe)*
The EmPro™ EPS/Nanoparasol™ EPS is indicated for use as a guidewire to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filter placement should be between 3.0 and 6.5 mm.

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

I. SUBMITTER

MicroVention, Inc.

35 Enterprise

Aliso Viejo, CA 92656

Establishment Registration No: 3013556777

Contact Person:

Sapna Singh

Regulatory Affairs, Director

Telephone: (714)-247-8162

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Date Prepared: March 27, 2023

II. DEVICE

Trade Names: EmPro™ Embolic Protection System (EP4514C-190, EP6514C-190); Nanoparasol™ Embolic Protection System (PNP4514C-190, PNP6514C-190)

Common Name: Embolic Protection System

Classification Name: 21 CFR 870.1250

Regulatory Class: II

Product Code: NTE

III. PREDICATE DEVICE

SpiderFX® Embolic Protection Device, K063204, EV3, Inc.

No reference devices were used in this submission

IV. DEVICE DESCRIPTION

MicroVention's Embolic Protection System (EPS) is marketed under two names: EmPro™ Embolic Protection System and Nanoparasol™ Embolic Protection System. The Embolic Protection System (EPS) is designed to capture and remove dislodged debris during a carotid interventional procedure. It consists of three basic components and additional accessories:

1) An Embolic Protection Device (EPD) consisting of a nitinol braided mesh filter with an atraumatic distal tip built on an integrated .014" PTFE coated stainless steel capture delivery wire.

2) A 3.5F delivery catheter with 150 cm length.

3) A 5F retrieval catheter with 150 cm working length. Accessories include a wire introducer, EPD loading cover, sheath introducer and a torque device. Catheters are provided in two separate dispenser coils.

The EmPro/Nanoparasol EPS is used in conjunction with a primary .014" compatible wire (not included in package) with the rapid exchange port to gain access across the lesion site. The .014" integrated Capture delivery wire is used as the primary guidewire for interventional devices such as a stent or PTA balloon catheter compatible with a .014" or .018" wire. The EPD loading cover protects the filter, is used to flush and load the filter into the delivery catheter.

Table 1: Device Information

Subject Device	Catalogue Number	Labeled Filter Size (mm)	Unconstrained Filter OD (mm)	Filter Length (in)	Reference Vessel Diameter (mm)
EmPro™ EPS	EP4514C-190	4.5	5.2	0.42	3.5 – 4.5
EmPro™ EPS	EP6514C-190	6.5	7.2	0.52	4.5 – 6.5
Nanoparasol™ EPS	NP4514C-190	4.5	5.2	0.42	3.5 – 4.5
Nanoparasol™ EPS	NP6514C-190	6.5	7.2	0.52	4.5 – 6.5

V. INDICATIONS FOR USE

The EmPro™ EPS/Nanoparasol™ EPS is indicated for use as a guidewire to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filter placement should be between 3.0 and 6.5 mm.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial equivalence of the EmPro™ EPS/Nanoparasol™ EPS to the SpiderFX® Embolic Protection Device was established through comparison of technological characteristics in terms of intended use, principle of operation, and fundamental design, comparative bench testing including functional and performance testing between subject and predicate devices and via animal and clinical studies.

The testing demonstrated demonstrates the technological similarity and equivalency of the subject and predicate devices. 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 EtO-sterilized (Table 2).

Table 2: Device Comparison Table

	SpiderFX® Embolic Protection Device (K063204)	EmPro™ EPS/Nanoparasol™ EPS
	Predicate Device	Subject Device
Indications for Use	The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filter placement should be between 3.0mm and 7.0mm.	The EmPro™ EPS/Nanoparasol™ EPS is indicated for use as a guidewire to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filter placement should be between 3.0 and 6.5 mm.
Device Classification	Class II, Temporary Carotid Catheter for Embolic Capture NTE 21 CFR 870.1250	Class II, Temporary Carotid Catheter for Embolic Capture NTE 21 CFR 870.1250
Device Components	embolic protection device (EPD) dual ended catheter for delivery and retrieval	embolic protection device (EPD) separate catheter for delivery and retrieval
Embolic Protection Device (Filter) Design and Materials	Nitinol mesh filter with 23 gauge blunt tip needle mounted on a 0.014" PTFE coated stainless steel guidewire	Nitinol mesh filter with an atraumatic distal tip built on an integrated .014" PTFE coated stainless steel capture delivery wire.
Filter Configuration	Eccentric	Concentric
Average Pore Size (mm)	245	177
Filter Basket Unconstrained OD (mm)	3.0,4.0,5.0,6.0 and 7.0	5.2 and 7.2
Filter Basket Length (cm)	2.7	2.0 and 2.3
Wire OD (in)	.014	.014
Overall Length (cm)	190 or 320	194
Wire Coating	PTFE	PTFE
Radiopaque Markers	Yes	Yes

Delivery Catheter Type	Rapid exchange	Peel away, rapid exchange
Delivery Catheter OD (Fr)	3.1	3.5
Delivery Catheter RX Section Length (cm)	25	30
Delivery Catheter Working Length (cm)	140	150
Retrieval Catheter OD (Fr)	4.2	5.0
Retrieval Catheter RX Section Length (cm)	25	30
Retrieval Catheter Working Length (cm)	140	150
Accessories	Introducer sheath and shaping mandrel	- wire introducer - EPD loading cover - sheath introducer - torque device
Method of Supply	Sterile and single use	Sterile and single use
Sterilization Method	Ethylene oxide	Ethylene oxide

VII. PERFORMANCE DATA

The following performance data were provided to demonstrate substantial equivalence:

- Sterilization validation
- EO residuals
- Package integrity (visual inspection, dye penetration, and seal strength)
- Shelf-life
- Biocompatibility per ISO 10993-1
- Mechanical testing
    - Dimensional verification
    - Deployment/retrieval force
    - EPD retrieval test
    - Peel away test
    - Tensile strength
    - Torque test
    - Buckle test

- Tracking/kink resistance
- Particulate capture
- Coating adherence
- Radial force
- Filter capacity
- Simulated use

Animal Study

The *in vivo* performance and safety of the EPD was evaluated in the porcine model. Six (6) animals were subjected to interventional treatment and devices were explanted 30 days post-operatively (4 animals) or 180 days post-operatively (2 animals). The following performance characteristics were evaluated during the intervention: preparation and introduction, tracking, deployment force, radiopacity, wall apposition, blood flowrate, device stability, retrieval force, vessel irregularities, and post intervention cine time. Post-intervention, thrombus formation, particulate capture, filter/stent damage, and neurological dysfunction were evaluated. In addition, histology was performed to evaluate impact of product use on local tissues. Results of the study demonstrate that the EPD performs as intended. The performance scores met or exceeded acceptance criteria is both intervention groups and all animals met the acceptance criteria for neurological assessments at both timepoints. Histological analysis of local tissues showed negligible vessel injury, inflammation, and neointimal response where the EPD was deployed.

Clinical Study

The CONFIDENCE study (IDE G140249) was a multicenter, single-arm, interventional study designed to evaluate the safety and effectiveness of the Casper™/Roadsaver™ Carotid Artery Stent used in conjunction with the EmPro™/Nanoparasol™ EPS in patients at high risk for adverse events from carotid endarterectomy (CEA) who required carotid revascularization. All patients with qualifying carotid artery stenosis (n = 256) were treated with the devices. The primary endpoint was the Major Adverse Event (MAE) composite consisting of death, stroke, or MI within 30 days of the index procedure plus ipsilateral stroke between 31 days and 12 months. The secondary endpoints included procedure success and technical success of the Casper™/Roadsaver™ Carotid Artery Stent and EmPro™/Nanoparasol™ EPS technical success.

In the Intent-To-Treat (ITT) population, the mean (SD) age was 69.6 (6.8) years, and the majority of the subjects were male (65.2% [n=167]). 95.3% [n=244] of subjects were not of Hispanic or Latino; 4.7% of subjects identified themselves as Hispanic or Latino. 91% [n=233] of subjects were white; 4.3% (n=11) identified themselves as Black or African American. Overall, these demographic characteristics are consistent with a typical cohort of subjects with carotid artery stenosis at high operative risk for CEA.

The primary endpoint was MAE, a composite measure of death, stroke, or MI within 30 days of the index procedure plus ipsilateral stroke 31–365 days after the procedure In the ITT population, 15 patients (5.9% [95% exact binomial CI: 3.89, 10.69]; p=0.0014) experienced a MAE. In the ITT analysis using multiple imputations for subjects who discontinued prematurely, the MAE rate was 6.2% (16/256). The upper limit of the 95% exact binomial CI was 9.22%, which was below the PG of 13.9%. Thus, the primary endpoint of the study was met.

Secondary endpoints include technical success and procedure success of the stent and embolic protection device technical success. EmPro™/Nanoparasol™ EPS technical success was achieved in 98.8% (253/256) of subjects.

Table 3: EmPro™/Nanoparasol™ EPS Performance Analysis	**ITT Population N=256(%)**
EPS successfully inserted	255 (99.6%)
EPS successfully deployed in subject (Technical Success)	253 (98.8%)
EPS successfully retrieved	255 (99.6%)
Vessel dissection at EPS filter site	0

General safety results: With respect to the EmPro™/Nanoparasol™ EPS, one patient had an SAE most likely due to a strong relationship to the device. This SAE was a Nervous System Disorder (Cerebrovascular Accident).

VIII. CONCLUSION

MicroVention concludes through a review of the non-clinical and clinical studies, the comparison of the device classification, indications for use, operating principle, and technological characteristics, that the subject device, EmPro™ EPS/Nanoparasol™ EPS is substantially equivalent to the predicate, SpiderFX® Embolic Protection Device. Any differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.