March 31, 2022

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

Re: K211120
Trade/Device Name: ERIC Retrieval Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: March 25, 2022
Received: March 28, 2022

Dear Sapna 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,

Naira Muradyan, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211120

Device Name
ERIC Retrieval Device

Indications for Use *(Describe)*
The ERIC Retrieval Device is indicated to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K211120 510(k) Summary

Trade Name:	ERIC™ Retrieval Device
Generic Name:	Percutaneous Catheter
Classification:	II, 21 CFR 870.1250, NRY
Submitted By:	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, USA
Contact:	Sapna Singh Director, Regulatory Affairs MicroVention, Inc. Sapna.Singh@MicroVention.com Tel: (714) 247-8000 x 8162
Date:	March 29, 2022
Predicate Device:	Trevo XP ProVue Retriever (6x25 mm), K143077 Trevo XP ProVue Retriever (4x30mm), K150616 Modified Trevo ProVue Retriever (3x20 mm and 4x20 mm), K132641
Reference Device:	Solitaire™ FR Revascularization Device (K113455)
Device Description:	The ERIC™ (**E**mbolus **R**etriever with **I**nterlinked **C**age) Retrieval Device is a mechanical thrombectomy device designed to restore blood flow by removing clots from vasculature in patients suffering from acute ischemic stroke. The device consists of retrieval spheres secured on a pusher wire that are designed to capture and remove blood clots from the neurovasculature. The device is inserted into a microcatheter to navigate to the target location and retrieve the thrombus while the device is withdrawn from the vessel.
Indications for Use:	The ERIC™ Retrieval Device is indicated to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic

stroke 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.

Comparison of Technological Characteristics with the Predicate Device:

The subject device, ERIC™ Retrieval Device, is substantially equivalent to the predicate device in terms of intended use, scientific technology, and fundamental design. A tabular comparison of the technological characteristics between the predicate device and subject device is provided below.

Table 1: Technological Characteristics Comparison

Device Characteristics	**Predicate Device**	**Subject Device**	**Comparison**
	Trevo XP ProVue (6x25 mm, K143077 and 4x30 mm, K150616)	**ERIC™ Retrieval Device**	
	Modified Trevo ProVue Retriever (3x20 mm and 4x20 mm K132641)		
Manufacturer	Stryker	MicroVention	N/A
Classification	21 CFR 870.1250, Class II	21 CFR 870.1250, Class II	Same
Device Classification Name	Catheter, Thrombus Retriever	Catheter, Thrombus Retriever	Same
Product Code	NRY	NRY	Same
Indications for Use	The Trevo XP ProVue Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke 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.	The ERIC Retrieval Device is indicated to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke 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.	Same
Target Population	Patients with symptoms of an ischemic stroke	Patients with symptoms of an ischemic stroke	Same
Anatomical Sites	Neurovasculature	Neurovasculature	Same

Device Characteristics	**Predicate Device**	**Subject Device**	**Comparison**
	Trevo XP ProVue (6x25 mm, K143077 and 4x30 mm, K150616)	**ERIC™ Retrieval Device**	
	Modified Trevo ProVue Retriever (3x20 mm and 4x20 mm K132641)		
Principal Device Dimensions & Materials			
Size (Retriever Diameter × Length) (mm)	3×20 4×20 4×30 6×25	3×15 4×42 3×20 6×26 3×25 6×35 4×18 6×44 4×24 4×30 4×36	Bench and animal testing have demonstrated that the different overall lengths of the subject device offerings do not raise new questions regarding safety and efficacy.
Stent & Core Wire (Shaft)	Nitinol	Nitinol	Same
Stent Radiopaque Wire	Platinum/Tungsten	None	Minor difference does not raise new questions regarding safety and efficacy. Both devices have radiopaque characteristics.
Distal Marker/Coil	Platinum/Tungsten	Tantalum	Similar. Both are commonly used medical grade materials. Material difference does not raise new questions of safety and efficacy.
Proximal Marker/Coil	304 Stainless Steel	Tantalum	Similar. Both are commonly used medical grade materials. Material difference does not raise new questions of safety and efficacy.
Solder	Gold/Tin	N/A	Minor difference does not raise new questions regarding safety and efficacy.
Hydrophilic Coating	Sodium Hyaluronate Mixture	None	Difference does not raise new questions of safety and efficacy. Hydrophilic coatings are commonly used to

Device Characteristics	Predicate Device Trevo XP ProVue (6x25 mm, K143077 and 4x30 mm, K150616) Modified Trevo ProVue Retriever (3x20 mm and 4x20 mm K132641)	Subject Device ERIC™ Retrieval Device	Comparison
			lubricate some vascular devices.
Pusher Shrink Tubing	None	Polyethylene	Polyethylene is a commonly used medical grade plastic. Difference does not raise new questions of safety and efficacy.
Additional Characteristics			
Packaging Materials and Configuration	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Bleached Sulfate carton	Minor difference does not raise new questions regarding safety and efficacy.
Supplied As	Sterile/Single Use	Sterile/Single Use	Same
Sterilization Method	Ethylene Oxide	Electron Beam	Minor difference in method does not raise new questions regarding safety and efficacy. Both devices demonstrate a SAL of 10^{-6}.

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:

Table 2: Verification and Validation Testing

Test Description	Test Method	Result	Conclusions
Dimensional Testing (Expanded Diameter & Device Overall Length)	Device attributes (overall device length and expanded outer diameter (OD) of the shaped section) were measured.	Pass	The longer overall length and smaller OD of the subject device offerings does not affect the performance of the device.

Test Description	Test Method	Result	Conclusions
Fluoroscopic Guidance Marker Testing	The radiopacity of device markers were assessed under fluoroscopy during non-clinical testing.	Pass	Both subject and predicate devices are sufficiently visible under fluoroscopy.
Advance/Retraction Force Testing	The advance and retract forces of the subject device in a tortuous model were compared with the forces measured for one or more predicate devices.	Pass	The advance and retract forces of the subject device were comparable with the forces measured for the predicate device.
Re-Sheathing Testing	The ability to re-sheath the device was evaluated compared with the predicate device.	Pass	The ability to re-sheath the subject device is comparable to that of the predicate device tested.
Radial Force Testing	The radial force of the subject device was measured by radially compressing the device and was compared with the radial forces measured for predicate device.	Pass	The radial force of the subject device is comparable to that of the predicate device tested.
Tensile Strength Testing	The peak tensile strength to failure in different sections of the subject device was evaluated and compared with that measured for the predicate device.	Pass	The system tensile strength of the subject device is comparable to that of the predicate device tested.
Kink Resistance Testing	Kink resistance of the subject device was evaluated when wrapped around a series of mandrels of decreasing radii until permanent deformation was observed or until the smallest radius was used.	Pass	Kink resistance of the subject device is equivalent to that of the predicate device tested.
Austenite Finish (A_f) Testing	A_f temperature testing of the subject device determined at what temperature the shape recovery transformation is complete upon heating and is a property of the pseudoelastic material used.	Pass	The A_f temperature of the subject device is less than the product use temperature (body temperature) and, thus, satisfies requirements for clinical applications.
Simulated Use/ Performance Testing	The ability to reliably deploy and use the subject device in a tortuous benchtop model was evaluated and compared with one or more predicate devices.	Pass	Simulated use testing was comparable with that of the predicate device.

Test Description	Test Method	Result	Conclusions
Corrosion Resistance Testing	Metallic components intended for fluid path contact were evaluated for signs of corrosion.	Pass	Corrosion resistance testing of the subject device showed no signs of corrosion.
Particulate Evaluation Testing	Particulate evaluation testing of the subject device was evaluated in a tortuous benchtop model and was compared with that of the predicate device.	Pass	Particulate evaluation was comparable with that of the predicate device.
Torque Response Testing	The torque ability of the subject device in a tortuous benchtop model was evaluated and compared with the predicate device.	Pass	Torque response testing indicated that the core wire of the subject device rotates freely with the proximal sphere and, thus, has equivalent torqueability compared to the predicate device.

Biocompatibility Evaluation:

The in vitro and in vivo biocompatibility safety studies performed on the terminally sterilized ERIC™ Retrieval Device have demonstrated the biocompatibility of the proposed device and support compliance with ISO 10993-1, '*Biological Evaluation of Medical Devices,*' and the FDA Biocompatibility Guidance.

Per ISO 10993-1, the ERIC™ Retrieval device is categorized as an external communicating device with limited exposure. The device was determined to be non-cytotoxic, non-sensitizing, non-irritating, non-toxic, non-pyrogenic, non-hemolytic, non-activating, and has no effect on coagulation of human plasma and hematological parameters. The results of the biocompatibility evaluation are summarized as follows:

Table 3: Biocompatibility Testing

Test	Test Summary	Conclusions
Cytotoxicity: L929 MEM Elusion Test	There was no biological reactivity (Grade 0) of the cells exposed to the test article extract.	Non-cytotoxic
Sensitization: Kligman Maximization Test in Guinea Pigs	The test article extracts elicited no reaction at the challenge (0% sensitization) following an induction phase.	Non-sensitizer
Intracutaneous Reactivity in White Rabbits	No evidence of irritation (score 0.0).	Non-irritating

Test	Test Summary	Conclusions
Systemic Injection Test in Mice	No biologically significant weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice was observed.	Systemically non-toxic
Rabbit Pyrogen Test (Material Mediated)	No rabbit showed an individual rise in temperature of 0.5 ºC. The temperature increases for the test animals were 0.0 ºC.	Non-pyrogenic
ASTM Blood Compatibility - Direct and Indirect Contact Hemolysis	The test article demonstrated 0.12% hemolysis in direct contact and 0.00% hemolysis in indirect contact.	Non-hemolytic
Unactivated Partial Thromboplastin Time Test	An average coagulation time of the test article showed no significant difference from the control.	No effect on coagulation of human plasma
Complement Activation Test (Direct Contact)	The plasma exposed to the test article for 90 minutes was found to exhibit no statistically significant increase in C3 and SC5b-9.	Non-activating
Platelet and Leukocyte Count Assay (Direct Contact)	The concentration of White Blood Cells (WBC) and Platelets (Plt) in human blood exposed to the test article was not statistically significantly decreased.	No effect on hematological parameters
Thrombogenicity	The test article had a thrombus formation score of "2" and was considered thromboresistant.	Non-thrombogenic

Sterilization, Shelf-Life, and Packaging Integrity:

The ERIC™ Retrieval Device is labeled as a single-use, sterile device. The sterilization process for the ERIC™ Retrieval Device has been successfully validated and process monitoring controls are in place to assure that the device is electron beam sterilized to achieve a minimum SAL of 10^{-6} with bacterial endotoxin < 2.15 EU/device.

Shelf-life studies per ASTM F1980 have been conducted for the ERIC™ Retrieval Device and establish that the product and packaging remain functional and sterile for the shelf-life period indicated on the label.

Animal Testing Summary:

Acute and chronic in vivo testing was conducted in a porcine model to evaluate safety and performance characteristics of the ERIC Retrieval Device in comparison to the predicate device, Trevo XP ProVue Retriever. Histological evaluation demonstrated that the tissue response to both test and control devices were similar. There was no evidence of perforation or dissection in vessels treated with either the test or control devices. There was no evidence of downstream thromboembolic or ischemic injury. Chronic study animals remained healthy, gained weight, and survived to scheduled termination. Study endpoints were met, and ERIC Retrieval Devices were shown to be safe and equivalent to the predicate device.

Clinical Study Data:

To support the substantial equivalence of the ERIC™ Retrieval Device (ERIC) to its predicate device cleared in the US [Trevo XP ProVue Retriever, Trevo], the clinical data collected from Endovascular Treatment in Ischemic Stroke follow-up Evaluation (ETIS) Observational Cohort Study (NCT03776877) was collected and analyzed.

ETIS is a prospective, multi-center, observational, Good Clinical Practice (GCP) compliant study conducted in France assessing the angiographic and clinical outcomes associated with the use of CE-marked thrombectomy devices [including the ERIC™ device, Trevo and Solitaire FR Revascularization Device (Solitaire)] that are intended to restore blood flow in patients experiencing acute ischemic stroke due to large intracranial vessel occlusion. This ongoing ETIS study was initiated in 2011 and has enrolled more than 14,000 subjects as of January 2022. The data presented in here represents an analysis population that is a subset of the ETIS study and includes all consecutive subjects treated by the ERIC™ device, Solitaire and Trevo at all 7 active sites from the beginning of the study to September 2018. The data analysis included the clinical, angiographic, and functional outcomes of two hundred six (N=206) patients treated with the ERIC™ device in comparison to N=1058 patients treated with Trevo or Solitaire. The angiographic and clinical outcomes demonstrate that the ERIC™ device performs similarly to the Trevo and Solitaire in terms of successful reperfusion rate and good clinical outcome (mRS 0-2) at 90 days based on available follow-up data in the two analysis groups. The ERIC™ device also exhibits a comparable safety profile, including similar rates of procedural complications, sICH, and 90-day all-cause mortality based on available follow-up data in the two analysis groups. One of the limitations of the ETIS study due to its design is the number of subjects with

missing data; therefore, the conclusions made from the ETIS study in support of this 510(k) are based on subjects with available follow-up data in both analysis groups.

All patients were selected for endovascular thrombectomy based on evaluation by a multi-disciplinary team of physicians including neuroradiologists and neurologists. Selection included patients with acute ischemic stroke (AIS), in relation to an occlusion of a large caliber intracranial artery of the anterior circulation, visible in imaging within a period of 6 hours after the onset of symptoms, either initially in combination with intravenous thrombolysis (IVT), or as recourse technique: after failure of treatment with IVT, or alone in case of contraindication to IVT. Both arms of the study included the use of thrombolytics. The ETIS study was conducted in accordance with the GCP guidelines and applicable regulatory requirements (FR, ICH E3-E6, ISO14155).

Primary Outcomes:

Primary Effectiveness Outcome

The primary effectiveness outcome was defined as achievement of an mTICI score of 2b or greater in the target vessel. The success criterion for this analysis is that the primary effectiveness outcome success rate for the ERIC device cohort is statistically non-inferior to the mTICI rate for the Trevo/Solitaire cohort.

Primary Safety Outcome

The primary safety outcome was defined as the occurrence of symptomatic intracerebral hemorrhage (sICH) within 24 hours post-procedure. The success criterion for this analysis is that the rate of occurrence of the primary safety outcome for the ERIC device cohort is statistically non-inferior to the sICH rate for the Trevo/Solitaire cohort.

Inclusion Criteria:

1. Age 18 and older (i.e., candidates must have had their 18th birthday)
2. Neuroimaging demonstrates acute ischemic stroke in a large vessel indicated for use with neurothrombectomy devices intended to restore blood flow
3. No upper or lower limits of the neurological severity at baseline (NIHSS)
4. With or without intravenous thrombolysis
5. Oral informed consent (patient and/or trustworthy person)

Exclusion Criteria:

1. Pregnant or breast-feeding women
2. Patient benefiting from a legal protection
3. Non-membership of a national insurance scheme

Study Results:
The study assessed the efficacy and safety of the ERIC™ Retrieval Device using marketed devices used in usual clinical practice in comparison to the predicate device, Trevo XP ProVue, and reference device, Solitaire.

Table 4: ETIS Study Outcomes: ERIC vs Trevo/Solitaire Cohort

ETIS Study Results	ERIC Device Cohort (N=206)		Trevo/Solitaire Cohort (N=1058)	
	n/N	Value [Rate (CI)]	n/N	Value [Rate (CI)]
Primary Effectiveness Outcome				
Successful reperfusion at end of procedure (mTICI 2b-3)	166/202	82.2% (76.9-87.5%)	842/1044	80.7% (78.2-83.1%)
Primary Safety Outcome				
Occurrence of sICH within 24h-48h*	7/169	4.1% (1.1-7.2%)	81/965	8.4% (6.6-10.2%)

*59 ERIC-treated patients and 37 Trevo/Solitaire patients without follow-up CT scan/MRI due to absence of symptoms (per site hospital usual care) were treated as absence of symptomatic intracerebral hemorrhage. The number of missing patients without follow-up CT/MRI in the ERIC-treated group is proportionally higher than the number of missing patients without follow-up CT/MRI in the Trevo/Solitaire-treated group. Therefore, the occurrence of sICH within 24-48 hours with the ERIC-treated patients could be higher than the confidence intervals presented in this table.

The primary effectiveness outcome results generated by treating the subjects with rescue mechanical thrombectomy device after failure of the primary intended device to achieve mTICI 2b or greater and missing subjects as failures are shown below.

Table 5: Primary Effectiveness Endpoint (mTICI 2b-3) – ERIC Device vs Trevo/Solitaire: Use of Rescue Mechanical Thrombectomy Device Considered Treatment Failure

Primary Effectiveness Endpoint	ERIC (N=206)		Trevo/Solitaire (N=1058)	
	n/N	Value	n/N	Value

Successful reperfusion at end of procedure (mTICI 2b-3)*	130/206	63.1%	639/1058	60.4%

*The effectiveness outcomes were considered as failures for missing subjects as well as those subjects with use of rescue mechanical thrombectomy device.

The secondary outcome for good clinical outcome (90-day mRS 0-2) is shown in the table below. The results of this analysis demonstrate that the 90-day mRS of the ERIC arm and the control arm are substantially equivalent based on available follow-up data.

Table 6: Secondary Outcome (90-day mRS) - ERIC vs Trevo/Solitaire

	ERIC (N=206)		**Trevo/Solitaire (N=1058)**	
	n/N	**Value**	**n/N**	**Value**
Secondary Outcome				
Good Clinical Outcome (90-day mRS 0-2)	67/136	49.3% (40-57.7%)	413/919	44.9% (41.7-48.2%)

Comparison of the primary safety and effectiveness outcomes and secondary outcome for the ERIC cohort versus the Trevo/Solitaire cohort from the ETIS study demonstrated that the ERIC device is substantially equivalent to the predicate device.

Conclusion:

The information presented in this 510(k) demonstrates the substantial equivalence between the predicate and the ERIC™ Retrieval Device regarding the design, construction materials, operating principle, bench testing, animal testing and clinical performance for the intended use.