

DE NOVO CLASSIFICATION REQUEST FOR BRAID EMBOLIZATION ASSIST DEVICE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Temporary coil embolization assist device for peripheral vascular use. A temporary coil embolization assist device is a prescription device intended for temporary use in the vasculature to mechanically assist in the embolization of aneurysms with embolic coils. The device is delivered into the vasculature with an endovascular approach. This device is not intended to be permanently implanted and is removed from the body when the procedure is completed.

NEW REGULATION NUMBER: 21 CFR 870.3325

CLASSIFICATION: Class II

PRODUCT CODE: QZU

BACKGROUND

DEVICE NAME: BraidE Embolization Assist Device

SUBMISSION NUMBER: DEN230064

DATE DE NOVO RECEIVED: September 19, 2023

SPONSOR INFORMATION: Rapid-Medical Ltd.
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INDICATIONS FOR USE

The BraidE Embolization Assist Device is indicated for use in the peripheral vasculature as a temporary endovascular device used to assist in the coil embolization of wide-necked peripheral aneurysms with a neck width ≤ 10 mm. A wide-necked peripheral aneurysm defines the neck width as ≥ 4 mm or a dome-to-neck ratio < 2 .

LIMITATIONS

The sale, distribution, and use of the BraidE Embolization Assist Device are restricted to prescription use in accordance with 21 CFR 801.109.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The BraidE Embolization Assist Device is a sterile single use endovascular device intended to provide temporary assistance for the coil embolization of wide-necked peripheral aneurysms. The BraidE is comprised of a nitinol braided mesh, stainless steel shaft, nitinol core wire and a handle. The device is shown in Figure 1. The braided mesh at the distal portion of the device is shown in Figure 2.



Figure 1. BraidE Embolization Assist Device with Handle.



Figure 2. BraidE Embolization Assist Device mesh region in both the expanded and contracted positions.

The shaft connects the mesh and the handle by the core wire that runs inside the shaft from the distal end of the mesh to the slider activation element in the handle. The mesh is expanded when the physician pulls the slider. Because the wires of the mesh are completely radiopaque, the physician sees the mesh under fluoroscopy and controls it until it conforms to the aneurysm neck morphology and vessel requirement.

SUMMARY OF NONCLINICAL/BENCH STUDIES

COMANECI TEST ARTICLES

Most of the nonclinical and bench studies used to support the BraidE Embolization Assist Device were leveraged from the Comaneci Embolization Assist Device (DEN170064) because the two devices are identical with the exception of a shorter length and new markers.

BIOCOMPATIBILITY/MATERIALS

The BraidE Embolization Assist Device is classified as an external communicating device of limited contact duration (< 24 hours) and is directly blood-contacting. Table 1 shows the device components and materials of construction that were evaluated for biocompatibility. Biocompatibility testing was leveraged from the Comaneci Embolization Assist Device (DEN170064) which shares relevant design features. The following biocompatibility endpoints were evaluated: hemocompatibility (complement activation, thrombogenicity, indirect hemolysis and direct hemolysis), cytotoxicity, sensitization, intracutaneous (intradermal) reactivity, acute systemic toxicity, and material-mediated pyrogenicity testing per International Standard Organization (ISO) 10993-1:2009/AC:2010 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing) and the Guidance for Industry and Food and Drug Administration Staff, “Use of International Standard ISO 10993-1, ‘Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process’”, issued September, 2023.

Table 1. Patient Contacting Materials of Construction of the BraidE Embolization Assist Device.

Name of Component	Materials used in Finished Devices
Distal Mesh	Nitinol Wire
Tip	Polypropylene and Nitinol
Core Wire	Nitinol with PTFE Coating
Markers	Platinum Iridium

SHELF LIFE/STERILITY

The shelf-life of the BraidE Embolization Assist Device has been established at 2.5 years based on a combination of real-time and accelerated aging testing equivalent to 2.5 years in accordance with ASTM F1980 - 07 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Testing was leveraged from the Comaneci Embolization Assist Device (DEN170064) which shares relevant design features. Following aging, the devices underwent additional package integrity testing in accordance with the following standards:

- ASTM F1929:2015 – Standard Test Method for Detecting Seal Leaks in Porous

Medical Packaging by Dye Penetration

- ASTM F2096:2011 – Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F 1886-16 Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection.

The Braide Embolization Assist Device was adopted into an existing, validated ethylene oxide (EtO) sterilization cycle (AAMI TIR28:2016). The sterilization cycle was assured by using the validated over kill (or the half-cycle) sterilization method qualified in accordance with ISO 11135:2014. Based on the validation results, a sterility assurance level (SAL) of at least 10^{-6} was achieved.

PERFORMANCE TESTING - BENCH

Performance testing, summarized in Table 2, was leveraged from the Comaneci Embolization Assist Device (DEN170064) which shares relevant design features.

Table 2. Summary of Non-Clinical Bench Testing.

Test	Test Purpose and Description
Tensile Strength	To verify that the tensile strength of each joint of the device complied with the requirements. Testing was performed with a calibrated tensile machine. The following joints were inspected: proximal connection, core wire to handle, shaft to handle, and distal connection.
Kink Resistance	To evaluate the ability of the device to reach tortuous vasculature without being kinked. Testing was performed with a calibrated kink measurement jig.
Functional and Microcatheter Compatibility	To evaluate the ability of the device to be delivered in the recommended compatible microcatheter through the tortuous vessels of a silicone vasculature model to the target site.
Corrosion	To evaluate the susceptibility of the device components to corrosion in a simulated physiological environment.
Tip Flexibility	To measure the maximum force deflected by the device tip. Testing was performed with a calibrated tensile machine.
Dimensional Verification	To verify various device dimensional attributes.
Particulate Evaluation	To measure the total quantity and size of particulates that the device may generate in a simulated use vascular model.
Radial Force/Crush	To demonstrate the ability of the distal mesh portion of the device to withstand external forces and to retain its structural integrity while being compressed from the embolic coil mass. Additionally, this testing was performed to measure the radial outward forces from the device to ensure the forces exhibited from the device will not cause serious vessel damage.
Coating Integrity	To evaluate the coating integrity of the core wire, which has a PTFE coating.

Test	Test Purpose and Description
Tracking Force/ Torque	To demonstrate the device can withstand typical tracking forces and procedural torquing of the device.
Simulated Use	To demonstrate device performance in a simulated in vitro anatomical model from entry through the femoral artery to the target site. The testing followed the procedural instructions outlined in the Directions for Use.

PERFORMANCE TESTING - ANIMAL

Animal study results was leveraged from the Comaneci Embolization Assist Device (DEN170064) which shares relevant design features. The animal study was conducted in accordance with Good Laboratory Practice (GLP) in a rabbit model of an elastase-induced neurovascular aneurysm to evaluate the acute (4 days) and chronic (28 days) safety and performance of the Comaneci Embolization Assist Device compared to a control device ((b)(4)). The study characterized aneurysmal healing by light microscopy and en face assessment of the luminal surface by scanning electron microscopy (SEM). The animal study also assessed overall performance and handling of the device, in-life health, systemic biological tolerance, vascular injury and in-vivo thrombogenicity.

For the gross, histological, and clinical chemistry evaluations at both the acute and chronic time points, the objectives of the study were:

- Successfully create elastase-induced saccular aneurysms in rabbits to compare test and control devices.
- Compare test and control devices with respect to tissue response, degree of aneurysm healing, and safety.

Angiographic evaluations were conducted at the time of termination in both test and control animals for both acute and chronic time points to assess blood flow through the treated region, presence or absence of intra-luminal filling of the embolized aneurysm, and presence or absence of embolic coils in the parent artery. Success criteria for this assessment included:

- Successful delivery of the test and control devices to the target location without major procedural device-related complications such as death, artery perforation or flow-limiting dissection or thrombosis.
- Absence of embolic coil prolapse in the parent artery.
- Absence of aneurysm intraluminal filling following device application.
- Less than 15% overall animal mortality.
- Comparable or better performance by semi-quantitative morphometric analysis in tissue sections treated with the subject device test articles when compared to tissue sections treated with the control test articles.
- Comparable or better histologic indicators of vessel wall healing such as: injury, inflammation and extent of endothelial loss as determined by light microscopy

and SEM in tissue sections exposed to the subject device test articles when compared to tissue sections exposed to the control test articles at 28 ± 2 days follow-up.

The non-clinical animal study concluded for the acute time point assessment that the parent artery was patent during coil embolization of aneurysms with both the control device ((b)(4)) and the test article (Comaneci Embolization Assist Device). There were 23 aneurysms created in 20 animals and all of these animals underwent successful coil embolization with no post-procedural mortalities and no angiographically-visible coil protrusions into the parent vessels. Recovery of the animals in both groups was associated with absence of morbidity, thrombosis, infection, hemorrhage, or downstream ischemia.

The non-clinical animal study concluded for the terminal assessments at the chronic time point that there were patent parent vessels with gross and histologic evidence of normal aneurysmal sac embolization. Upon explant using high-resolution radiographical assessment, visible mild embolic coil protrusion was observed in two aneurysms treated with the Comaneci Embolization Assist Device and one aneurysm treated with the ((b)(4)). Light microscopic and SEM evaluations of adjacent, proximal, and distal regions of the device vessel contact zones showed an absence of perforations, dissections, erosions, or thrombus formation. The distal skeletal muscles were also observed to be absent of any thrombus formation.

SUMMARY OF CLINICAL INFORMATION

The BraidE Embolization Assist Device was supported by two clinical data sets, 1) historical post-market data from an outside the United States (OUS) retrospective collection of intracranial aneurysms treated with the Comaneci device (DEN170064), and 2) case studies of the Comaneci device used in the peripheral vasculature reported in the clinical literature.

Historical post-market data

The BraidE Embolization Assist Device and the Comaneci Embolization Assist Device (DEN170064) share clinically relevant design features and similar procedural steps. Therefore, available clinical data from both peripheral and neurovascular use of the Comaneci device was used to support the safety and effectiveness of the BraidE. The clinical study design and results are further summarized below.

Design

The Comaneci Embolization Assist Device was evaluated in an OUS post-market retrospective study from 63 consecutively treated patients with 64 intracranial aneurysms between March to December 2017 at two sites: Walton Center in Liverpool, United Kingdom and University Hospital St. Ivan Rilski in Sofia, Bulgaria. The patients were followed for up to 3-months post-procedure. Table 3 below summarizes the patient demographic and baseline intracranial aneurysm characteristics.

Imaging data for technical success and safety were independently analyzed by the Angiography and Noninvasive Imaging Core Lab at University of California – Los Angeles in Los Angeles, California. Adverse events (AE) were adjudicated independently by the Department of Neurology at the University of Southern California.

Table 3. Patient Demographics and Baseline Intracranial Aneurysm Characteristics Treated with the Comaneci Embolization Assist Device

N	64 intracranial aneurysms in 63 patients
Ruptured/Unruptured (N=64)	Ruptured - 51/64 (80%) Unruptured- 13/64 (20%)
Age (N=63)	57 (34-73) years
Gender* (N=63)	34 Female, 29 Male
Mean Neck Size (N=64)	4.2 mm (Range 1.9-11.5 mm)
Aneurysm Location (N=64)	Anterior Communicating Artery (AComm) - 17 (26.6%)
	Anterior Cerebral Artery (ACA) - 1 (1.5%)
	Anterior Choroidal Artery - 1 (1.5%)
	Anterior Inferior Cerebellar Artery (AICA) - 1 (1.5%)
	Basilar Tip - 3 (4.7%)
	Middle Cerebral Artery (MCA) - 10 (15.6%)
	Ophthalmic - 6 (9.4%)
	Posterior Communicating Artery (PComm) - 17 (26.6%)
	Superior Cerebellum Artery (SCA) - 4 (6.2%)
	Internal Carotid Artery (ICA) - 4 (6.2%)
Mean Number of Coils per Aneurysm (N=64)	6.09 (Range 1-19)

* Race/ethnicity data were not available.

Data was collected using a pre-specified case report form (CRF) that was designed to collect technical procedural related information regarding the use of the subject device and device-related serious adverse events (SAEs). Data collected in the CRF included:

- Whether the Comaneci Embolization Assist Device was used as a first-choice device.
- Number of device attempts.
- Intracranial aneurysm neck coverage.
- Number of embolization coils deployed.
- Number of re-expansions of the Comaneci Embolization Assist Device during the procedure.
- Intracranial aneurysm occlusion using the Raymond-Roy scale.
- Alternative treatment(s) used.
- Time the Comaneci Embolization Assist Device was left inside the target vessel while opened.

- Incidences of rupture, hemorrhage, thrombotic events, deaths, coil prolapse, and coil entanglement.

The clinical study also evaluated radiopacity of the device to verify it can be visualized under fluoroscopic guidance. No pre-specified inclusion or exclusion criteria were used in the retrospective study analysis, and the treating physician used their own judgment to determine if a patient was eligible for treatment with the subject device. In the De Novo request, the training plan for the use of the device with the novel adjustment feature of the mesh region was provided as part of the review.

Results

No mortality or subject device-coil entanglements were reported. Table 4 shows the ten (10) SAEs reported from the retrospective study and an additional one AE of intracranial aneurysm rupture associated with the patient. A limitation of the retrospective study was that the data was only collected at 2 sites outside the US and the AE data reported was limited to device-related SAEs including intracranial aneurysm or vessel rupture or hemorrhage, death, thrombotic events, and technical success data such as coil entanglement and prolapse into the parent artery. Therefore, these retrospective data are not a full representation of the safety profile of the Comaneci Embolization Assist Device.

Table 4. Adverse Events Reported in Retrospective Study of the Comaneci Embolization Assist Device.

Adverse Event	Number of Events	Incidence Rate (%) N=63 Patients	Time of Event Onset	95% Unadjusted Confidence Intervals (%) ¹
Symptomatic thrombotic event/ischemic stroke	2	3.17	24 and 4 hours post-procedure	(0.39, 11.0)
Vasospasm	1	1.59	During procedure	(0.04, 8.53)
Contralateral SCA hemorrhage	1	1.59	During procedure	(0.04, 8.53)
Left SCA occlusion	1	1.59	3 months post-procedure	(0.04, 8.53)
Cerebellar ataxia	1	1.59	24 hours post-procedure	(0.04, 8.53)
Paresis for right leg	1	1.59	48 hours post-procedure	(0.04, 8.53)
Apathy, memory disorder, personality changes	1	1.59	48 hours post-procedure	(0.04, 8.53)
Mild hemiparesis	1	1.59	48 hours post-procedure	(0.04, 8.53)

Adverse Event	Number of Events	Incidence Rate (%) N=63 Patients	Time of Event Onset	95% Unadjusted Confidence Intervals (%) ¹
Mild aphasia	1	1.59	48 hours post-procedure	(0.04, 8.53)
Aneurysm Rupture*	1	1.59	Pre-procedure	(0.04, 8.53)

(*) Patient admitted with ruptured intracranial aneurysm.

(¹) All 95% confidence intervals (CIs) are unadjusted. As such, the CI is provided to show the variability only and should not be used to draw any statistical conclusions.

Table 5 shows the post-hoc analysis using descriptive statistics of the total incidence of treated patients experiencing at least one AE recorded within 3-months post-procedure.

Table 5. Post-hoc Safety Analysis

N (Patients)	Number of Patients That Experienced Any AE Event	AE Rate (%)	95% Unadjusted Lower Bound CI (%)*	95% Unadjusted Upper Bound CI (%)*
63	7	11.1%	5.55	23.15

*All 95% CIs are unadjusted. As such, the CI is provided to show the variability only and should not be used to draw any statistical conclusions.

Table 6 shows the technical success rate (defined post-hoc as the successful coil embolization of the target intracranial aneurysm without the incidence of embolic coil entanglement, ensnarement, prolapse, or protrusion into the parent vessel) was observed in 93.65% (59/63) of the patients treated in the retrospective case series study. No cases of coil entanglement or ensnarement were observed, and 4 cases (6.35% (4/63)) of coil prolapse were noted. None of the four events were associated with any clinical abnormalities or sequelae with the known follow-up data collected within 3-months post-procedure.

Table 6. Post-hoc Technical Success Analysis

N (Patients)	Technical Success Rate (%)	95% Unadjusted Lower Bound CI (%)*	95% Unadjusted Upper Bound CI (%)*
63	93.65	84.53	98.24

*All 95% CIs are unadjusted. As such, the CI is provided to show the variability only and should not be used to draw any statistical conclusions.

Peripheral use of the Comaneci device

Three publications report use of the Comaneci device for the treatment of complex peripheral Visceral and Renal Artery Aneurysms (VRAAs) in 6 patients, Table 7:

Table 7. Case reports of Peripheral use of the Comaneci device

Publication	Aneurysm Description	Safety Observations	Effectiveness Observations
Maingard, et al.	Distal renal aneurysm, at the renal hilum. Bi-lobed and wide-necked, 25 mm aneurysm.	No immediate or periprocedural complications.	Aneurysm remained occluded on follow-up CTA with no evidence of parent arterial compromise or parenchymal infarction.
Maingard, et al.	Multiple splenic aneurysms. Largest at the hilar bifurcation was a wide-necked, 20 mm aneurysm.	No immediate or periprocedural complications.	Aneurysm remained occluded on follow-up CTA at 6 weeks post-procedure.
Avital, et al.	One complicated renal artery aneurysm.	None reported.	The aneurysm was completely excluded. Follow-up CT angiography demonstrated preserved patency of the parent and branch vessels.
Avital, et al.	One superior mesenteric artery aneurysm and one splenic artery aneurysm.	While resheathing and removing the Comaneci device, one of the coils was tangled in the Comaneci struts and pulled into the splenic artery. Nontarget embolization of the splenic artery resulted and diffuse splenic infarcts were noted.	The aneurysms were completely excluded. Follow-up CT angiography demonstrated preserved patency of the parent and branch vessels.
Avital, et al.	Two splenic artery aneurysms.	Follow-up CT revealed a subcapsular infarct in the upper pole.	The aneurysms were completely excluded.
Hargis, et al.	One renal artery aneurysm at the distal bifurcation. Wide-necked, 20 mm aneurysm. Multiple segmental vessel arose from the aneurysm sac. The Comaneci device was deployed in two selected segmental vessels to preserve distal perfusion.	The simultaneous use of the devices was performed without difficulty or complication intraoperatively.	Follow up to 9 months showed no evidence of a residual/recurrent aneurysm.

The case studies provide evidence for clinical success in the peripheral vasculature since all visceral aneurysms were completely excluded/occluded during the embolization procedure. All but one of the procedures were concluded with complete patency of the parent and branch vessels. During exclusion of one splenic artery aneurysm, one of the coils that protruded from the sac was tangled in the Comaneci struts and was inadvertently pulled back into the splenic artery, leading to non-target embolization of the splenic artery. To mitigate this type of situation, the device labeling recommends verifying the coil's stability in the aneurysm by deflating the mesh before coil detachment.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling includes instructions for use for the physician and satisfies the requirements of 21 CFR § 801.109 for prescription devices. The labeling includes:

- Detailed instructions on proper device preparation, appropriate model and size selection, and use to assist in the coil embolization of aneurysms.
- Expertise needed for the safe use of the device.
- A detailed summary of the device technical parameters including compatible delivery catheter dimensions.
- Summary of the clinical testing results and case studies in the peripheral vasculature, including a detailed summary of the device- and procedure-related complications and adverse events.
- A shelf life.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with a temporary coil embolization assist device for peripheral vascular use and the measures necessary to mitigate these risks.

Table 8. Identified Risks to Health and Mitigation Measures

Risks to Health	Mitigation Measures
Tissue or vessel damage leading to: • Dissection • Perforation • Hemorrhage • Vasospasm	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Thromboembolic event	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Coils ensnarement	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Infection	Sterilization validation Pyrogenicity testing Shelf life testing Labeling

Adverse tissue reaction	Biocompatibility evaluation
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SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the temporary coil embolization assist device for peripheral vascular use is subject to the following special controls:

1. Clinical performance testing of the device must demonstrate the device performs as intended under anticipated conditions of use and must evaluate all adverse events, including tissue or vessel damage that could lead to dissection, perforation, hemorrhage, or vasospasm, thromboembolic events, and coil ensnarement.
2. Animal testing under anticipated use conditions must demonstrate the device can be delivered to the target location in the vasculature and is compatible with embolic coils, and must evaluate all adverse events, including damage to vessels or tissues assessed by histology.
3. Non-clinical performance testing must demonstrate the device performs as intended under anticipated conditions of use, including:
 - a. Mechanical testing to demonstrate the device can withstand anticipated tensile, torsional, compressive, and tip deflection forces;
 - b. Mechanical testing to evaluate the radial forces exerted by the device;
 - c. Simulated use testing to demonstrate the device can be delivered to the target location through simulated vasculature that has clinically relevant tortuosity and that the device is compatible with embolic coils;
 - d. Dimensional verification testing; and
 - e. Radiopacity testing.
4. The patient-contacting components of the device must be demonstrated to be biocompatible.
5. Performance data must support the sterility and pyrogenicity of the device.
6. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.
7. The labeling must include:
 - a. A detailed summary of the device technical parameters, including compatible delivery catheter dimensions and device sizing information;
 - b. A summary of the clinical testing results, including a detailed summary of the technical success rate, device- and procedure-related complications and adverse events; and
 - c. A shelf life.

BENEFIT-RISK DETERMINATION

In general, given the similarities of anatomy, disease conditions and device characteristics, the risks and benefits observed in the neurovascular experience are expected to approximate those in the peripheral vasculature. Furthermore, the peripheral case studies reported showed similar observations those seen in the neurovasculature.

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a neurovascular clinical study and peripheral vascular case studies described above. Probable device-related risks or adverse events include thrombo-embolic events, tissue or vessel damage including dissection, perforation, hemorrhage, or vasospasm, entanglement of the device with embolic coils, coil prolapse into the parent vessel, death, infection, adverse tissue reaction. Based on the results of the neurological retrospective case series submitted in support of this De Novo request with complete CRFs provided for all subjects, 11.1% (7/63) of treated subjects experienced a serious neurological adverse event within 3-months post-procedure. The associated types of adverse events can occur due to the underlying disease state such that their device- or procedure-relatedness is unclear. In addition, this adverse event rate is similar to that published in the scientific literature for balloon assisted coiling of intracranial aneurysms with cleared balloon occlusion catheters. Three case studies were evaluated to assess the risk of using the device for treatment of complex peripheral visceral and renal artery aneurysms (VRAAs). In one case, entanglement of the device with embolic coils occurred, leading to non-target embolization of the splenic artery. This risk is consistent with the neurovascular experience and is partly mitigated by a recommendation in the labeling to verify coil stability in the aneurysm by deflating the mesh before coil detachment.

The probable benefits of the device are also based on nonclinical laboratory and animal studies as well as data collected in neurovascular clinical study and peripheral vascular case studies as described above. The benefit of the subject device is that it is a temporary device which allows for blood to be supplied to the distal vasculature during the coil embolization procedure unlike balloon occlusion catheters. The post-hoc analysis of the neurological retrospective case series showed that 93.65% (59/63) of treated subjects experienced successful coil embolization of their target intracranial aneurysm without the incidence of embolic coil entanglement, ensnarement, prolapse, or protrusion into the parent vessel. In the peripheral case studies, all visceral aneurysms were completely excluded during the embolization procedure, and all but one of the procedures were concluded with complete patency of the parent and branch vessels.

One of the limitations of the submitted neurovascular clinical data is the uncertainty associated with study design (retrospective case series) and limited number of subjects (64). Only the neurological adverse events that could be attributed to the device or procedure were specified in the CRF. The majority of patients had ruptured intracranial aneurysms (51/64 = 79.7%) and many of the neurological adverse effects may be attributed to the underlying disease state of these patients with ruptured intracranial aneurysms. Another limitation was the limited peripheral vascular experience. However, the similarity in observations between the neurovascular and peripheral experience provides support for the relevance of neurovascular data and justifies the reliance on limited peripheral data for the present decision.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

The BraidE Embolization Assist Device is indicated for use in the peripheral vasculature as a temporary endovascular device used to assist in the coil embolization of wide-necked peripheral aneurysms with a neck width ≤ 10 mm. A wide-necked peripheral aneurysm defines the neck width as ≥ 4 mm or a dome-to-neck ratio < 2 .

The probable benefits outweigh the probable risks for the BraidE Embolization Assist Device. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the BraidE Embolization Assist Device is granted and the device is classified as follows:

Product Code: QZU

Device Type: Temporary coil embolization assist device for peripheral vascular use

Regulation Number: 21 CFR 870.3325

Class: II