DE NOVO CLASSIFICATION REQUEST FOR COMANECI EMBOLIZATION ASSIST DEVICE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Temporary coil embolization assist device.** A temporary coil embolization assist device is a prescription device intended for temporary use in the neurovasculature to mechanically assist in the embolization of intracranial aneurysms with embolic coils. The device is delivered into the neurovasculature 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 882.5955

CLASSIFICATION: Class II

PRODUCT CODE: PUU

BACKGROUND

DEVICE NAME: Comaneci Embolization Assist Device

SUBMISSION NUMBER: DEN170064

DATE DE NOVO RECEIVED: September 28, 2017

SPONSOR INFORMATION: Rapid-Medical Ltd.
Carmel Building, POB 337
Yokneam, Yokneam 2069205
Israel

INDICATIONS FOR USE

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

LIMITATIONS

The sale, distribution, and use of the Comaneci 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 Comaneci Embolization Assist Device consists of three device models: Comaneci, Comaneci Petit, and Comaneci 17 (see Table 1). The Comaneci Embolization Assist Device is intended for temporary use and is introduced through an endovascular approach to the neurovasculature to assist in the coil embolization of wide-necked intracranial aneurysms with a neck width $\leq$ 10 mm. The device consists of a nitinol fine wire mesh region at the distal end mounted on a flexible shaft that expands and contracts when the physician pulls a core wire that is coated with polytetrafluoroethylene (PTFE) and connected to a handle with a control slider made of a styrene-butadiene copolymer (Figures 1 and 2). The fine wire mesh region on the Comaneci Embolization Assist Device is unique in that it is not self-expandable but is directly controlled by the physician to size this region of the device to the parent vessel. The wires of the mesh are radiopaque, which allows the physician to visualize the mesh under fluoroscopy. The Comaneci and Comaneci Petit models are delivered through a microcatheter with an internal diameter (ID) of 0.021 inches and the Comaneci 17 is delivered through a microcatheter with an ID of 0.017 inches. The devices are packaged in a sterile pouch and are intended for single use only.

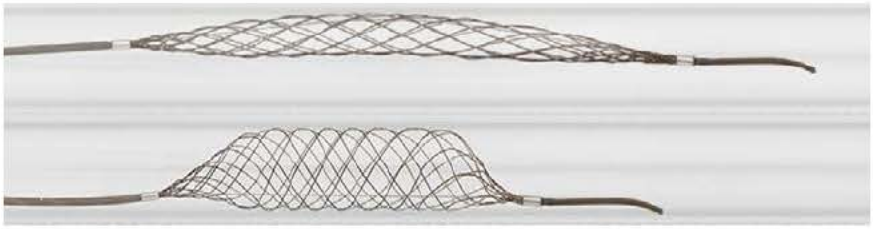

Figure 1. Comaneci Embolization Assist Device mesh region in both the expanded and contracted positions.

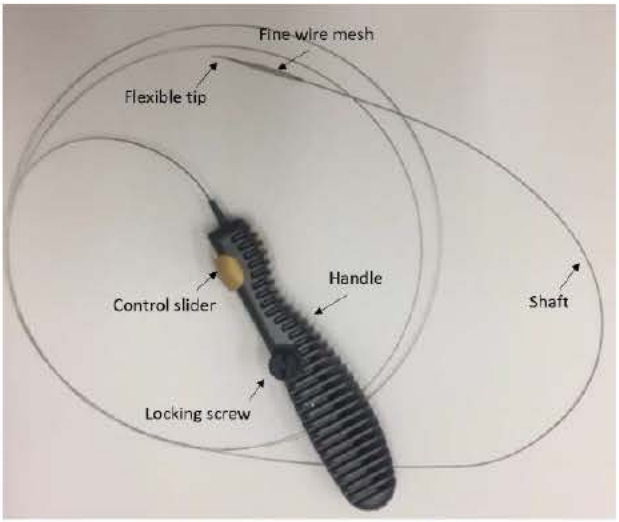

Figure 2. Comaneci Embolization Assist Device with Handle.

Table 1. Comaneci Embolization Assist Device Dimensions

	Comaneci	Comaneci Petit	Comaneci 17
Weight	36 g	36 g	36 g
Contracted Mesh Length	32 mm	24 mm	22 mm
Expanded Mesh Length	25 mm (4.0 mm simulated vessel)	21 mm (3.0 mm simulated vessel)	16 mm (3.0 mm simulated vessel)
Total Length (Not Including Handle)	1825 mm	1827 mm	1787 mm

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The Comaneci Embolization Assist Device is classified as an external communicating device of limited contact duration (< 24 hours) and is directly blood-contacting. Table 2 shows the device components and materials of construction that were evaluated for biocompatibility. The applicable biocompatibility endpoints evaluated are 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 Center for Devices and Radiological Health (CDRH) 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 on June 16, 2016.

Table 2. Patient Contacting Materials of Construction of the Comaneci Embolization Assist Device.

Name of Component	Materials used in Finished Devices
Distal Mesh	Nitinol Wire
Tip	(b) (4) and Nitinol
Core Wire	Nitinol with PTFE Coating
Markers	(b) (4)

SHELF LIFE/STERILITY

The Comaneci Embolization Assist Device is sterilized with ethylene oxide (EtO). The sterility of the Comaneci Embolization Assist Device was assured by using the validated (b) (4) 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. The sterilization validation included (b) (4) The surveillance of the sterilization results was performed using biological indicators and complies with the requirements in ISO 11138-2:2006. Bioburden testing was performed on packaged devices using the validation test method according to ISO 11737-1:2006, "Sterilization of Medical Devices

- Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Product."

Bacterial endotoxin testing using the limulus amebocyte lysate (LAL) test method was also evaluated for the Comaneci Embolization Assist Device to meet the endotoxin limit of less than 2.15 endotoxin units (EU)/device according to United States Pharmacopeia (USP) <161> Transfusion and Infusion Assemblies and Similar Medical Devices. This evaluation is important because there is the risk of vessel dissection with the subject device, which can result in direct contact with cerebrospinal fluid (CSF) and introduce the risk of infection in the brain if there are bacterial endotoxins remaining on the device.

The Comaneci Embolization Assist Device is packaged inside a (b) (4) blister box. The blister box is closed by a cover to prevent device movement during handling and shipment. The blister box is placed inside a heat-sealed Tyvek® pouch. The seal is designed for EtO sterilization providing a microbiological barrier and allowing the passage of moisture and EtO to enable the sterilization of the packaged contents.

The Comaneci Embolization Assist Device and its packaging has been validated for a shelf life of 2.5 years. The test units for shelf-life testing contained a blister box with hoop and tube that simulated the device and handle to represent the packaged device configuration and weight. The test units were also packaged in Tyvek pouches and underwent two EtO sterilization cycles. The Comaneci Embolization Assist Device also underwent additional package integrity testing in accordance with the following standards:

- ASTM D4169:2009 – Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980:2011 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1929:2004 – 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)

PERFORMANCE TESTING - BENCH

Non-clinical bench testing was provided to demonstrate that the device would function adequately under simulated conditions of use and mitigate risks to health associated with device breakage and failure. The non-clinical bench testing is described in Table 3 based on the device risk analysis, FDA guidances for embolization devices and guidewires, and the following standards:

- ISO 10555-1 (2013): Intravascular Catheters – Sterile and Single-use Catheters – Part 1: General Requirements.

- ISO 11070 (2014): Sterile Single-use Intravascular Introducers, Dilators and Guidewires.
- ISO 25539-2 (2012): Cardiovascular Implants – Endovascular Devices – Part 2: Vascular Stents.

Before non-clinical bench testing, the final finished Comaneci Embolization Assist Device underwent 2 full cycles of EtO sterilization followed by inspection to ensure the devices met specifications.

Table 3. Summary of Non-Clinical Bench Testing for the Comaneci Embolization Assist Device.

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 neurovasculature tortuosity 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 neurovascular 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.
Tracking Force/ Torque	To demonstrate the device can withstand typical tracking forces and procedural torqueing of the device as the device is intended to be used in the neurovasculature which can have significant tortuosity.
Simulated Use	To demonstrate device performance in a simulated in vitro anatomical model from entry through the femoral artery to the

Test	Test Purpose and Description
	target neurovasculature. The testing followed the procedural instructions outlined in the Directions for Use.

PERFORMANCE TESTING - ANIMAL

An animal study was conducted in accordance with Good Laboratory Practice (GLP) in a rabbit model of an elastase-induced 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 (HyperGlide™ Balloon Catheter). 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 (HyperGlide Balloon Catheter) and the subject 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 HyperGlide Balloon Catheter. 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

Clinical data from an outside the United States (US) post-market retrospective collection of intracranial aneurysms treated with the subject device was used to support the safety and effectiveness of the Comaneci Embolization Assist Device in the subject De Novo request. The clinical study design and results are further summarized below.

Design:

The Comaneci Embolization Assist Device was evaluated in an outside the US 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 4 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 were adjudicated independently by the Department of Neurology at the University of Southern California.

Table 4. 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)

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 (AEs). 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 in the outside the US retrospective study of the Comaneci Embolization Assist Device. Table 5 shows the ten (10) serious AEs 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 serious AEs 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, this retrospective data is not a full representation of the safety profile of the Comaneci Embolization Assist Device.

Table 5. 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)
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 6 shows the post-hoc analysis using descriptive statistics of the total incidence of treated patients experiencing at least one AE from the retrospective post-market case series from 2 outside the US sites of 63 patients recorded within 3-months post-procedure.

Table 6. 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 7 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 7. 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.

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.

POSTMARKET EVALUATION

A post-market study will be conducted to collect data on the safety of the Comaneci Embolization Assist Device in US patients. This is a post-market, prospective, multi-center study of US patients with wide-necked intracranial aneurysms that requires adjunctive assistance with coil embolization during the surgical procedure. This post-market study will evaluate the safety of the subject device used in the real-world clinical setting in the US to assess how well US physicians are trained on the use of the subject device based on the novel adjustment feature of the mesh region of the Comaneci Embolization Assist Device.

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 intracranial 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, 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 use of a temporary coil embolization assist device and the measures necessary to mitigate these risks.

Table 8. Identified Risks to Health and Mitigation Measures

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

SPECIAL CONTROLS

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

1. Clinical performance testing of the device must demonstrate the device performs as intended for temporary use as an endovascular device to assist in the coil embolization of intracranial aneurysms and must evaluate all adverse events, including tissue or vessel damage that could lead to dissection, perforation, hemorrhage, or vasospasm, thrombo-embolic events, and coil entanglement.
2. The patient-contacting components of the device must be demonstrated to be biocompatible.
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 in the neurovasculature and is compatible with embolic coils;
d. Dimensional verification testing;
e. Radiopacity testing; and
f. Performance testing to evaluate the coating integrity and particulates under simulated use conditions.

4. Animal testing under anticipated use conditions must evaluate all adverse events, including damage to vessels or tissues.
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. Instructions for use;
   b. A detailed summary of the device technical parameters, including compatible delivery catheter dimensions and device sizing information;
   c. A summary of the clinical testing results, including a detailed summary of the device- and procedure-related complications and adverse events; and
   d. A shelf life.

BENEFIT-RISK DETERMINATION

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical study described above. Device-related risks or adverse events could 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 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. This serious adverse event rate is not all deemed to be device- or procedure-related because many of the subjects treated had ruptured intracranial aneurysms and these adverse events may occur because of the disease state of these subjects. 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.

The probable benefits of the device are also based on nonclinical laboratory and animal studies as well as data collected in a clinical study as described above. The benefit of the subject device is that it is not permanently implanted and 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 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.

One of the limitations of the submitted 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. The neurological AE profile in the real world may change with a greater variety of patients to assist in the coil embolization of unruptured intracranial aneurysms. The neurological AE profile was obtained from only two sites, both of which are located outside the US. Thus, there may be additional uncertainty as to how well the submitted clinical data will predict the safety of this device in US clinical use in a broader patient population. Due to these limitations, a planned postmarket study will supplement existing evidence and gather additional experience on the safety profile of this device in the US.

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

The probable benefits outweigh the probable risks for the Comaneci 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 Comaneci Embolization Assist Device is granted and the device is classified as follows:

> Product Code: PUU
> Device Type: Temporary coil embolization assist device
> Regulation Number: 21 CFR 882.5955
> Class: II