April 24, 2019

Rapid-Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: DEN170064
Trade/Device Name: Comaneci Embolization Assist Device
Regulation Number: 21 CFR 882.5955
Regulation Name: Temporary coil embolization assist device
Regulatory Class: Class II
Product Code: PUU
Dated: September 28, 2017
Received: September 28, 2017

Dear Janice Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Comaneci Embolization Assist Device, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Comaneci Embolization Assist Device, and substantially equivalent devices of this generic type, into Class II under the generic name temporary coil embolization assist device.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 29, 2017 automatically classifying the Comaneci Embolization Assist Device in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II.

On September 28, 2017, FDA received your De Novo requesting classification of the Comaneci Embolization Assist Device. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Comaneci Embolization Assist Device into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Comaneci Embolization Assist Device can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – 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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety

and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the temporary coil embolization assist device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Samuel Raben, Ph.D. at 240-402-6629.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
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