DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Claret Medical, Inc.
Mr. Zachary Woodson
VP of QA/RA June 1, 2017
1745 Copperhill Parkway, Ste. 1
Santa Rosa, CA 95403

Re: DEN160043
Sentinel® Cerebral Protection System
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 870.1251
Regulation Name: Temporary catheter for embolic protection during transcatheter intracardiac procedures
Regulatory Classification: Class II
Product Code: PUM
Dated: September 19, 2016
Received: September 20, 2016

Dear Mr. Woodson:

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 Sentinel® Cerebral Protection System, a prescription device under 21 CFR Part 801.109 that is indicated for the following:

> The Sentinel® Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 – 10 mm in the left common carotid.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Sentinel® Cerebral Protection System, and substantially equivalent devices of this generic type, into class II under the generic name, temporary catheter for embolic protection during transcatheter intracardiac procedures.

FDA identifies this generic type of device as:

> **Temporary catheter for embolic protection during transcatheter intracardiac procedures.** This device is a single use percutaneous catheter system that has (a) blood filter(s) at the distal end. This device is indicated for use while performing transcatheter intracardiac procedures. The device is used to filter blood in a manner that may prevent

embolic material (thrombus/debris) from the transcatheter intracardiac procedure from traveling towards the cerebral circulation.

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 new 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. 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** classifying the device type.

On September 20, 2016, FDA received your De Novo requesting classification of the Sentinel® Cerebral Protection System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Sentinel® Cerebral Protection System 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 the Sentinel® Cerebral Protection System indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Device failure leading to debris embolization and stroke or death	Non-clinical Performance Testing Animal Testing Clinical Performance Testing
Impeded or disrupted blood flow leading to peripheral ischemia	Non-clinical Performance Testing Animal Testing Clinical Performance Testing Labeling
Device incompatibility with transcatheter intracardiac procedure device leading to prolonged treatment time or device failure	Non-clinical Performance Testing Animal Testing Clinical Performance Testing Labeling
Adverse tissue reaction	Biocompatibility Evaluation
Infection	Sterilization Validation Shelf Life Testing

	Labeling
Vascular Injury due to device delivery, deployment, placement, or retrieval	Non-clinical Performance Testing Animal Testing Clinical Performance Testing Labeling

In combination with the general controls of the FD&C Act, the temporary catheter for embolic protection during transcatheter intracardiac procedures is subject to the following special controls:

1. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    a. Simulated-use testing in a clinically relevant bench anatomic model to assess the following:
        i. Delivery, deployment, and retrieval, including quantifying deployment and retrieval forces, and procedural time
        ii. Device compatibility and lack of interference with the transcatheter intracardiac procedure and device
    b. Tensile strengths of joints and components, tip flexibility, torque strength, torque response and kink resistance
    c. Flow characteristics
        i. The ability of the filter to not impede blood flow
        ii. The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow
    d. Characterization and verification of all dimensions

2. Animal testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed:
    a. Delivery, deployment, and retrieval, including quantifying procedural time
    b. Device compatibility and lack of interference with the transcatheter intracardiac procedure and device
    c. Flow characteristics
        i. The ability of the filter to not impede blood flow
        ii. The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow
    d. Gross pathology and histopathology assessing vascular injury and downstream embolization

3. All patient contacting components of the device must be demonstrated to be biocompatible.

4. Performance data must demonstrate the sterility of the device components intended to be provided sterile.

5. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

6. Labeling for the device must include:
    a. Instructions for use;
    b. Compatible transcatheter intracardiac procedure devices;
    c. A detailed summary of the clinical testing conducted; and
    d. A shelf life and storage conditions.

7. Clinical performance testing must demonstrate:
    a. The ability to safely deliver, deploy, and remove the device;
    b. The ability of the device to filter embolic material while not impeding blood flow;
    c. Secure positioning and stability of the position throughout the transcatheter intracardiac procedure; and
    d. Evaluation of all adverse events including death, stroke, and vascular injury.

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

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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.

If you have any questions concerning this classification order, please contact Sadaf Toor at 301-796-6381.

Sincerely,

Angela C. Krueger -S
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Angela C. Krueger
Acting Deputy Director
for Engineering and Science Review
Office of Device Evaluation
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