December 21, 2021

Spectranetics, Inc.
Ms. Sondra Chandler
Regulatory Affairs Specialist II
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: DEN210024
Trade/Device Name: CavaClear Laser Sheath
Regulation Number: 21 CFR 870.5125
Regulation Name: Laser-powered inferior vena cava filter retrieval catheter
Regulatory Class: Class II
Product Code: QRJ
Dated: June 24, 2021
Received: June 25, 2021

Dear Ms. Chandler:

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 CavaClear Laser Sheath, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The device is intended for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the CavaClear Laser Sheath, and substantially equivalent devices of this generic type, into Class II under the generic name laser-powered inferior vena cava filter retrieval catheter.

FDA identifies this generic type of device as:

> **Laser-powered inferior vena cava filter retrieval catheter**. A laser-powered inferior vena cava (IVC) filter retrieval catheter is a percutaneous catheter that uses a laser to ablate tissue and is intended to facilitate in the detachment and removal of indwelling IVC filters.

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.

On June 25, 2021, FDA received your De Novo requesting classification of the CavaClear Laser Sheath. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CavaClear Laser Sheath 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 CavaClear Laser Sheath 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 to health are infection, adverse tissue reaction, device damage resulting in embolic concern, soft tissue damage, and IVC filter damage resulting in clinical sequelae. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	**Mitigation Measures**
Infection	Sterilization validation Shelf life testing Pyrogenicity testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Device damage during use resulting in clinical sequelae such as embolic concern or prolonged procedure	Non-clinical performance testing Clinical performance testing
Soft tissue damage from laser, such as IVC injury, extravasation, and perforation	Laser generator compatibility testing *In-vivo* safety testing, Clinical performance testing Labeling Training
IVF filter damage, including fracture and embolization, due to laser interaction	Non-clinical performance testing Clinical testing Labeling Training

In combination with the general controls of the FD&C Act, the laser-powered inferior vena cava filter retrieval catheter is subject to the following special controls:

1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
   i. Evaluation of major and minor complications associated with IVC filter removal; and
   ii. Evaluation of success rates of IVC filter removal.
2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

i. Dimensional testing must demonstrate that the device is compatible with the intended anatomy and compatible with all labeled accessories.
ii. Mechanical testing on all joints must demonstrate that the device can withstand tensile and torsional forces encountered under challenging clinical use conditions.
iii. Simulated use testing must demonstrate that the device can be inserted, tracked, activated, and removed without device damage and that the device is able to function as intended (e.g., remove IVC filter without damage) under challenging clinical use conditions.
iv. Performance testing must demonstrate that the product is visible under fluoroscopic techniques.
v. Performance testing must demonstrate that the device does not kink when subjected to clinically relevant tortuosity.

3) Compatibility testing with laser generators must include:
   i. Electrical safety, electromagnetic compatibility (EMC) testing, and electromagnetic interference (EMI) testing must be conducted for all devices that contain electrical components.
   ii. Software verification, validation, and hazard analysis must be conducted for all devices that contain software.
   iii. Laser output characterization and performance testing, including verification of calibration reliability, energy output, and repetition rate, and laser lifetime testing, must be conducted.
4) All patient-contacting components must be demonstrated to be biocompatible.
5) Performance data must demonstrate the sterility and non-pyrogenicity of patient contacting components of the device that are provided sterile.
6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and system functionality over the established shelf life.
7) *In vivo* safety testing must demonstrate that the device does not cause soft tissue damage or device damage under worst case clinical use conditions.
8) Labeling must include the following:
   i. A detailed summary of the device technical parameters and materials of the device;
   ii. A summary of the clinical performance testing conducted with the device; and
   iii. A shelf life.
9) A training program must be provided to ensure that users can safely and reliably use the device per its instructions for use.

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 laser-powered inferior vena cava filter retrieval catheter 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/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 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/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).

If you have any questions concerning the contents of the letter, please contact Eleni Whatley at 301-796-6372.

Sincerely,

Brian D. Pullin -S

for Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health