



February 10, 2020

Bluegrass Vascular Technologies, Inc.
Gabriele Niederauer, Ph.D.
CEO & President
12500 Network Boulevard, Suite 308
San Antonio, Texas 78249

Re: DEN190038

Trade/Device Name: Surfacer Inside-Out Access Catheter System

Regulation Number: 21 CFR 870.1342

Regulation Name: Reverse central venous recanalization system

Regulatory Class: Class II

Product Code: QJH

Dated: August 15, 2019

Received: August 15, 2019

Dear Dr. Niederauer:

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 Surfacer Inside-Out Access Catheter System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Surfacer Inside-Out Access Catheter System is intended to obtain central venous access to facilitate catheter insertion into the central venous system for patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Surfacer Inside-Out Access Catheter System, and substantially equivalent devices of this generic type, into Class II under the generic name Reverse central venous recanalization system.

FDA identifies this generic type of device as:

Reverse central venous recanalization system. A reverse central venous recanalization system is a prescription device for obtaining central venous access to facilitate catheter insertion into the central venous system. Reverse recanalization involves the initiation of an access path from within the vein and then progressing to the skin for patients with upper body venous occlusions or other conditions that preclude central venous access by other methods.

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 March 21, 2016 automatically classifying the Surfacar Inside-Out Access Catheter System 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 August 15, 2019, FDA received your De Novo requesting classification of the Surfacar Inside-Out Access Catheter System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Surfacar Inside-Out Access Catheter 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, for the previously stated indications for use, the Surfacar Inside-Out Access Catheter System 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 Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Embolization caused by component fracture	Clinical performance testing Non-clinical performance testing
Death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, hematoma; or delays to therapy from failure to achieve central venous access	Clinical performance testing Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the reverse central venous recanalization system is subject to the following special controls:

- (1) Clinical performance testing must fulfill the following:
 - (i) Demonstrate the ability to safely deliver, deploy, and remove the device; and
 - (ii) Evaluate all adverse events including death, bleeding, damage to non-target tissue and organs, blood vessel perforation or rupture, and hematoma.

- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - (i) Simulated-use testing in a clinically relevant bench anatomic model to assess the delivery, deployment, and retrieval of the system;
 - (ii) Compatibility with other devices labeled for use with the device;
 - (iii) Tensile strengths of joints and components,
 - (iv) Kink resistance of system components;
 - (v) Radiopacity of components used to monitor procedure under fluoroscopy;
 - (vi) Characterization and verification of all dimensions; and
 - (vii) Leakage of air or fluid.
- (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:
 - (i) Instructions for use, including a description of compatible devices;
 - (ii) A detailed summary of the clinical testing conducted; and
 - (iii) The shelf life and storage conditions.

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 Reverse central venous recanalization system 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 Finn Donaldson at 301-796-9579.

Sincerely,

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