



Site Saver, Inc. d/b/a Lineus Medical  
% Dawn Norman  
Partner  
MRC Global, LLC  
9085 East Mineral Circle, Suite 110  
Centennial, Colorado 80112

May 27, 2021

Re: DEN190043

Trade/Device Name: SafeBreak® Vascular  
Regulation Number: 21 CFR 880.5220  
Regulation Name: Intravenous catheter force-activated separation device  
Regulatory Class: Class II  
Product Code: QOI  
Dated: September 17, 2019  
Received: September 18, 2019

Dear Dawn Norman:

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 SafeBreak® Vascular, a prescription device under 21 CFR Part 801.109 with the following indications for use:

SafeBreak® Vascular is intended to separate when excessive tension is exerted across a peripheral IV administration set. When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient's IV catheter.

SafeBreak® Vascular is intended to aid in reduction of peripheral IV mechanical complications requiring IV replacement.

SafeBreak® Vascular is intended to be used on peripheral IV catheters in adults and adolescent populations eighteen (18) years of age and older receiving intermittent or continuous infusions with an electronic pump.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SafeBreak® Vascular, and substantially equivalent devices of this generic type, into Class II under the generic name intravenous catheter force-activated separation device.

FDA identifies this generic type of device as:

**Intravenous catheter force-activated separation device.** An intravenous (IV) catheter force-activated separation device. An intravenous catheter force-activated separation device is placed in-

line with an intravenous catheter and an intravascular administration set, including any administration set accessories. It separates into two parts when a specified force is applied. The device is intended to reduce the risk of IV catheter failure(s) requiring IV catheter replacement.

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 September 18, 2019, FDA received your De Novo requesting classification of the SafeBreak<sup>®</sup> Vascular. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SafeBreak<sup>®</sup> Vascular 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 SafeBreak<sup>®</sup> Vascular 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
Delays of therapy due to failure of device to function as expected (e.g., if separation force too low)	Performance data, Non-clinical performance testing, and Labeling
Mechanical complications (e.g., IV dislodgement, IV infiltration, occlusion, and phlebitis events requiring IV replacement) due to failure of device to function as expected (e.g., if separation force too high)	Performance data, Non-clinical performance testing, and Labeling
Infection	Sterilization validation, Shelf life testing, Non-clinical performance testing, and Labeling
Air embolism	Non-clinical performance testing, and Labeling

Adverse tissue reaction	Biocompatibility evaluation, Pyrogenicity testing, and Non-clinical performance testing
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In combination with the general controls of the FD&C Act, the intravenous catheter force-activated separation device is subject to the following special controls:

1. Performance data must be provided to demonstrate clinically acceptable performance for the intended use of the device.
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. Separation force testing;
  - ii. Validation of anti-reconnect features;
  - iii. Air and liquid leakage testing, both before and after separation;
  - iv. Luer connection testing;
  - v. Flow rate testing;
  - vi. Particulate testing; and
  - vii. Microbial ingress testing.
3. The device must be demonstrated to be biocompatible.
4. Performance testing must demonstrate that the device is sterile and non-pyrogenic.
5. Performance testing must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.
6. Device labeling must include:
  - i. Instructions for use; and
  - ii. A discussion of catheter dressings intended to be used with the device.

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](mailto: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 intravenous catheter force-activated separation 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/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](mailto: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 Florencia Wilson at 240-402-9978.

Sincerely,

Courtney H. Lias, Ph.D.  
Acting Director  
OHT3: Office of GastroRenal, ObGyn,  
General Hospital and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health