September 29, 2023

Lineus Medical
% Dawn Norman
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K231957
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: June 30, 2023
Received: July 3, 2023

Dear Dawn Norman:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231957

Device Name
SafeBreak® Vascular

Indications for Use *(Describe)*
SafeBreak® Vascular is intended to separate when excessive tension is exerted across intravenous (IV) and intraosseous (IO) administration sets. When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient's IV or IO catheter.

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

SafeBreak® Vascular is intended to be used on peripheral IV catheters, midlines, peripherally inserted central catheter (PICCs), central venous catheters (CVCs), IV ports and port needles, and IOs in adults and pediatric populations two (2) weeks of age and older receiving intermittent or continuous infusions with an electronic pump.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K231957

Date Prepared:	**September 29, 2023**
Company:	Lineus Medical 179 North Church Ave, Suite 202 Fayetteville, AR 72701
Primary Contact:	Dawn Norman, MS Partner, MRC Global Phone: 618-604-3064 Dawn.Norman@askmrcglobal.com
Company Contact:	Vance Clement Chief Executive Officer Lineus Medical Phone: 901-351-9270 vance@lineusmed.com
Trade Name:	SafeBreak® Vascular
Common Name:	Intravenous Catheter Force-Activated Separation Device
Classification:	Class II
Regulation Number:	21 CFR 880.5220
Panel:	General Hospital
Product Code:	QOI
Primary Predicate:	K223486, SafeBreak® Vascular Manufacturer: Lineus Medical
Reference Device:	K230266, Orchid Safety Release Valve Manufacturer: Lineus Health Sciences

Device Description:
SafeBreak® Vascular is placed in-line with an intravenous or intraosseous catheter and an intravascular administration set, including any administration set accessories. It separates into two parts when a specified force is applied. The device has been shown to reduce the risk of IV catheter failure(s) requiring IV catheter replacement. When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient's IV or IO catheter.

SafeBreak® Vascular is provided sterilized by Ethylene Oxide. The product is single use only and is not designed for reprocessing or re-sterilization by the user.

The purpose of this 510(k) is to expand the indications for use of the product to include use in peripheral IV catheters, midlines, peripherally inserted central catheters (PICCs), central venous catheters (CVCs), IV ports and port needles, and IOs, in adult and pediatric populations two (2) weeks of age and older.

Indications for Use:
SafeBreak® Vascular is intended to separate when excessive tension is exerted across intravenous (IV) or intraosseous (IO) administration sets. When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient's IV or IO catheter. SafeBreak® Vascular is intended to aid in reduction of IV and IO mechanical complications requiring IV and IO replacement. SafeBreak® Vascular is intended to be used on peripheral IV catheters, midlines, peripherally inserted central catheters (PICCs), central venous catheters (CVCs), IV ports and port needles, and IOs, in adults and pediatric populations two (2) weeks of age and older receiving intermittent or continuous infusions with an electronic pump.

Substantial Equivalence:
SafeBreak® Vascular is intended to separate when excessive tension is exerted across an IV or IO administration set. SafeBreak® Vascular is intended to aid in reduction in IV or IO mechanical complications requiring IV or IO replacement. The subject SafeBreak® Vascular has the identical materials, technological characteristics, and operating principle, as the predicate device.

The safety and effectiveness of the subject device has been verified and validated and all are substantially equivalent. Thus, it can be concluded that the subject SafeBreak® Vascular does not raise different questions about safety and effectiveness.

Device Comparison

	K231957 Subject	K223486 Predicate	Assessment of Differences
Indications for Use	SafeBreak® Vascular is intended to separate when excessive tension is exerted across intravenous (IV) and intraosseous (IO) administration sets. When SafeBreak® Vascular separates, fluid flow is stopped from the infusion pump and blood flow is stopped from the patient's IV or IO catheter. SafeBreak® Vascular is intended to aid in reduction of IV and IO mechanical complications requiring IV and IO replacement. SafeBreak® Vascular is intended to be used on peripheral IV catheters, midlines, peripherally inserted central catheters (PICCs), central venous catheters (CVCs), IV ports and port needles, and IOs in adult and pediatric populations two (2) weeks of age and older, receiving intermittent or continuous infusions with an electronic pump.	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 pediatric populations greater than one (1) year of age receiving intermittent or continuous infusions with an electronic pump.	Substantially Equivalent Device usage modified to include use in midlines, PICCs CVCs, IV ports, and IOs, in addition to peripheral IV catheters. Patient population modified from greater than one (1) year of age to two (2) weeks of age and older. The safety and effectiveness of use of the reference device in the patient population of two (2) weeks and older has been established. Data and clinical literature support the safety and effectiveness of the subject device in peripheral IV catheters, midlines, PICCs, CVCs, IV ports, and IOs, in adult and pediatric patient populations two (2) weeks of age and older. The change does not raise any different questions of safety or effectiveness.

	K231957 Subject	K223486 Predicate	Assessment of Differences
Materials	• Makrolon • Polycarbonate • Saint-Gobain • INEOS ABS Lustran • Silicone	Identical	Substantially Equivalent Subject and predicate materials are unchanged and identical.
Separation force	1-5 lbf	1-5 lbf	Identical; Substantially Equivalent
Environment of Use	Hospital	Hospital	Identical; Substantially Equivalent
Principle of Operation	The subject SafeBreak® Vascular connects to the needleless connector found in the existing IV or IO extension set and to the existing IV or IO administration set via luer connectors. Upon installation of the SafeBreak® Vascular, an infusion can occur. Upon tension the SafeBreak® Vascular separates and the valve on each end of the device closes, stopping flow.	The subject SafeBreak® Vascular connects to the needleless connector found in the existing IV extension set and to the existing IV administration set via luer connectors. Upon installation of the SafeBreak® Vascular, infusion can occur. Upon tension the SafeBreak® Vascular separates and the valve on each end of the device closes, stopping flow.	Identical; Substantially Equivalent

	K231957 Subject	K223486 Predicate	Assessment of Differences
Vascular Access Type	Peripheral intravenous catheter, central venous catheter, intraosseous catheter	Peripheral intravenous catheter	All data, benefit-risk assessment, and clinical literature support the safety and effectiveness of the subject device in peripheral IV catheters, midlines, PICCs, CVCs, IV ports and port needles, and IOs, this change in vascular access type does not raise any different questions of safety or effectiveness.
For Use with Electronic Pump	Yes	Yes	Identical; Substantially Equivalent
Single Use	Yes	Yes	Identical; Substantially Equivalent
Continuous and Intermittent Infusion	Yes	Yes	Identical; Substantially Equivalent

Clinical Data:
The randomized and non-randomized clinical studies sponsored and conducted by Lineus Medical on the SafeBreak® Vascular device in the previous DEN190043 support the safety and effectiveness of the device in adolescents and adults. Review of clinical literature and pediatric extrapolation supports the use of the device in intravenous (midlines, PICCs, CVCs, IV ports,) and intraosseous administration lines in adults and pediatric populations.

Conclusion:
The subject SafeBreak® Vascular has the identical materials, technological characteristics, dimensions, and construction, and similar operating principle, to the predicate device, as demonstrated through performance and clinical testing. The subject and predicate devices are intended to separate upon application of tension to stop fluid flow in both directions between the administration set tubing and extension tubing, thus, the expansion in the indications for use does not affect the safety and effectiveness of the subject device.

The conducted benefit-risk assessment and clinical literature review demonstrate that the differences in the indications for use do not raise any new or different questions of safety or effectiveness. The information provided in this submission demonstrates that the subject device, SafeBreak® Vascular is substantially equivalent to its predicate device, SafeBreak® Vascular, cleared under K223486.

Therefore, it is concluded that the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device.