March 16, 2023

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

Re: K222791
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

Dear Dawn Norman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 16, 2022. Specifically, FDA is updating this SE Letter for a correction to the 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Dr. David Wolloscheck, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 301-796-1480, David.wolloscheck@fda.hhs.gov.

Sincerely,

David Wolloscheck, Ph.D.
Acting 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

October 16, 2022

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

Re: K222791
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 15, 2022
Received: September 15, 2022

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Payal Patel
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)*
K222791

Device Name
SafeBreak® Vascular

Indications for Use *(Describe)*
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.

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.

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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K222791

Date Prepared:	March 7, 2023
Company:	Lineus Medical 179 North Church Ave, Suite 202 Fayetteville, AR 72701
Primary Contact:	Dawn Norman 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:	DEN190043, SafeBreak® Vascular Manufacturer: Lineus Medical
Reference Device:	K212064, Orchid SRV™ Manufacturer: Linear Health Sciences, LLC

Device Description:
SafeBreak® Vascular 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 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 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 special 510(k) is to expand the separation force tolerance of SafeBreak® Vascular to 1-5 lbf.

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.

Substantial Equivalence:
The subject SafeBreak® Vascular is intended to separate when excessive tension is exerted across a peripheral IV administration set. The separation force tolerance of SafeBreak® Vascular is being expanded to 1-5 lbf. The subject SafeBreak® Vascular is intended to aid in reduction in peripheral IV mechanical complications requiring IV replacement. The subject SafeBreak® Vascular has the same intended use, same or similar materials, same or similar technological characteristics, the same operating principle, as the predicate and reference devices, respectively.

The safety and effectiveness of the subject device has been verified and validated and are 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

	K222791 Subject	DEN190043 Predicate	Assessment of Differences
General Device Characteristics			
Indications for Use	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.	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.	Identical; Substantially Equivalent
Materials	• Makrolon • Polycarbonate • Saint-Gobain • INEOS ABS Lustran • Silicone	• Makrolon • Polycarbonate • Saint-Gobain • INEOS ABS Lustran • Silicone	Identical; Substantially Equivalent

	K222791 Subject	DEN190043 Predicate	Assessment of Differences
Separation force	1-5 lbf	4 ± 1 lbf	Substantially equivalent. Both the predicate and reference devices have demonstrated the safety and effectiveness of separation forces. The change in tolerance of the subject device separation force does not raise any different questions of safety or effectiveness.
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 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.	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
Vascular Access Type	Peripheral intravenous catheter	Peripheral intravenous catheter	Identical; Substantially Equivalent
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

Performance Testing:

Mechanical testing (i.e., Separation Force Testing) of the SafeBreak® Vascular supports the safety and effectiveness of the expansion of the pull force range in the subject device. The pull force range specification was supported by the reference device.

Conclusion:

The subject SafeBreak® Vascular has similar intended use, and identical materials, technological characteristics, and operating principle compared to the predicate device. In addition, performance testing and engineering analysis support the expansion of the separation force specification, compared to the reference device. The difference in technology does not affect the safety and effectiveness of the subject device.

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