Linear Health Sciences, LLC
℅ Jessica Czamanski
Project Engineer
RQM+
2790 Mosside Blvd #800
Monroeville, Pennsylvania 15146

Re: K212064
Trade/Device Name: Orchid Safety Release Valve™
Regulation Number: 21 CFR 880.5220
Regulation Name: Intravenous Catheter Force-Activated Separation Device
Regulatory Class: Class II
Product Code: QOI
Dated: March 8, 2022
Received: March 9, 2022

Dear Jessica Czamanski:

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)*
K212064

Device Name
Orchid Safety Release Valve(TM)

Indications for Use *(Describe)*
The Linear Health Sciences™ Orchid Safety Release Valve™ is a tension-activated accessory for single patient use and placed between the existing IV administration set and IV extension set connection. The Orchid SRVTM is intended for use with electronic IV pumps in peripheral IV catheter applications where tension may act on the IV tubing. The Orchid SRVTM is designed to allow flow to an IV catheter. When excessive tension acts on the line, the Orchid SRVTM separates and closes the flow path in both directions. The Orchid SRVTM can be used during intermittent and continuous infusion.

The Orchid SRVTM is intended to aid in reduction of peripheral IV mechanical complications requiring IV replacement.

The Orchid SRVTM is for use with patients eighteen (18) years of age and older.

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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510(k) SUMMARY

K212064

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92.

I. Submitter

Submitter's Name:	Linear Health Sciences, LLC
Contact Person:	Mr. Daniel Clark President
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Email:	dan.clark@linearsciences.com
Date Preparation:	April 4, 2022

II. Application Correspondent

Contact's Name:	RQM+
Contact Person:	Jessica Czamanski Project Engineer, Regulatory Consultant
Address:	2790 Mosside Blvd #800 Monroeville, PA 15146
Telephone:	(412) 816-8147
Email:	jczamanski@rqmplus.com

III. Subject Device

Trade Name:	Orchid Safety Release Valve™
Common Name:	Quick Disconnect Accessory
Classification Name:	Intravenous Catheter Force-Activated Separation Device
Product Classification:	Class II
Regulation Number:	21 CFR §880.5220
Product Code:	QOI

IV. Predicate Device

Manufacturer:	Site Saver, Inc. d/b/s Lineus Medical
Device Name:	SafeBreak® Vascular
510(k) Number:	DEN190043
Product Classification:	Class II
Regulation Number:	21 CFR §880.5220

V. Device Description

The Orchid Safety Release Valve™ or Orchid SRV™ connects via standard luer-locking connection, allowing flow during IV therapy. The Orchid SRV™ is designed to allow the device to separate into two halves when longitudinal tension exceeds the SRV tension window (between 1-4.2 lbf), automatically closing the flow path to both IV extension set and IV administration set. Following separation, a component of the Orchid SRV™ is left attached to each side of the infusion system to protect the intraluminal pathway. Upon separation, replacement of the SRV™ is necessary. Follow institutional policy to replace the SRV™, or at least every seven (7) days.

VI. Intended Use

The Linear Health Sciences™ Orchid Safety Release Valve™ is a tension-activated accessory, provided sterile and for single use, in line with an IV administration set and peripheral IV extension set on a patient. The Orchid SRV™ provides a quick separation feature that allows the device to quickly separate into two halves upon tension, closing the flow path to prevent leakage. The device is intended to reduce the risk of IV catheter failure, requiring IV catheter replacement.

VII. Indications for Use

The Linear Health Sciences™ Orchid Safety Release Valve™ is a tension-activated accessory for single patient use and placed between the existing IV administration set and IV extension set connection. The Orchid SRV™ is intended for use with electronic IV pumps in peripheral IV catheter applications where tension may act on the IV tubing. The Orchid SRV™ is designed to allow flow to an IV catheter. When excessive tension acts on the line, the Orchid SRV™ separates and closes the flow path in both directions. The Orchid SRV™ can be used during intermittent and continuous infusion.

The Orchid SRV™ is intended to aid in reduction of peripheral IV mechanical complications requiring IV replacement.

The Orchid SRV™ is for use with patients eighteen (18) years of age and older.

VIII. Comparison of Technological Characteristics with the Predicate Devices

The subject and predicate devices are accessories that allow separation by force-activation used in infusion and/or IV administration. Both devices are intended to be connected via standard luer lock mechanisms. Both devices have the same intended use, same material types, similar technological characteristics, and same operating principle. Although the difference in technological characteristics is specific to the force required for separation of the two halves of each device, each device performs according to its own specifications. Both devices are intended to aid in reduction of the occurrence of dislodgement, therefore, the difference in technology do not affect the safety and effectiveness of the device and is substantially equivalent.

The following table (**Table 5-1**) provides an overview of general technological characteristics in comparison to the predicate device.

Table 5-1: General Technological Characteristics Comparison

Product Features	**Subject** Linear Health Sciences' Orchid Safety Release Valve™ (K212064)	**Predicate** Site Saver, Inc./ Lineus Medical SafeBreak Vascular (DEN190043)	**Substantial Equivalence Determination**
Classification	Class II	-same-	
Product Code	QOI	-same-	
Regulation Number	21 CFR §880.5220	-same-	
Device Classification Name	Intravenous Catheter Force-Activated Separation Device	-same-	
Indications for Use	The Linear Health Sciences™ Orchid Safety Release Valve™ is a tension-activated accessory for single patient use and placed between the existing IV administration set and IV extension set connection. The Orchid SRV™ is intended for use with electronic IV pumps in peripheral IV catheter applications where tension may act on the IV tubing. The Orchid SRV™ is designed to allow flow to an IV catheter. When excessive tension acts on the line, the Orchid SRV™ separates and closes the flow path in both directions. The Orchid SRV™ can be used during intermittent infusion and continuous infusion. The Orchid SRV™ is intended to aid in reduction of peripheral IV mechanical complications requiring IV replacement. The Orchid SRV™ is for use with patients eighteen (18) years of age and older.	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.	The subject and predicate devices are intended to reduce dislodgement during IV infusion. However, the Orchid SRV has a lower separation force, which allows the device to prevent dislodgement when using securement methods that have lower pull forces.
Materials	Polycarbonate and silicone	-same-	

Table 5-1: General Technological Characteristics Comparison

Product Features	**Subject** Linear Health Sciences' Orchid Safety Release Valve™ (K212064)	**Predicate** Site Saver, Inc./ Lineus Medical SafeBreak Vascular (DEN190043)	**Substantial Equivalence Determination**
Environment of Use	Hospital	-same-	
Provided Sterile	Yes	-same-	
Principle of Operation	The Orchid Safety Release Valve™ has luer lock connections that will lock the device in place during use. The female luer connects to an administration set while the male luer connects to a vascular access device hub or extension set. Once connected the device allows for continuous flow. The Orchid SRV will separate into the male and female subassemblies, upon a tension event, automatically closing the flow path, while maintaining sterility and preventing fluid leakage form the device.	The 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 principle of operation for the subject and predicate devices is the same.
User Profile	Physician or clinical personnel with clearance to administer IV sets and related products	-same-	
Separation Force	1-4.2 lbf	4 ± 1 lbf	The lower limit of the Orchid Safety Release Valve's separation force of 1-4.2 lbf was specifically designed to provide subject device separation prior to securement device failure even for those securement devices that come in at the lower end of the pull force spectrum. Some medical adhesives are specifically formulated to require a lower pull force due to the usage on elderly, fragile skin, or

			those at risk of increased IV dislodgement. The Orchid SRV's use specifications that work across the low end of the range provide benefit to these patients. Performance testing performed to demonstrate that device conforms to specification.
Vascular access Catheter Type	Peripheral catheter	-same-	
For Use with Electronic Pump	Yes	-same-	
Single Use	Yes	-same-	
Continuous and Intermittent Infusion	Yes	-same-	

Table 5-1: General Technological Characteristics Comparison

Product Features	Subject Linear Health Sciences' Orchid Safety Release Valve™ (K212064)	Predicate Site Saver, Inc./ Lineus Medical SafeBreak Vascular (DEN190043)	Substantial Equivalence Determination
Sterilization	Ethylene Oxide	-same-	
SAL	10^{-6}	-same-	

IX. Performance Data

The following performance data was considered in support of the substantial equivalence determination.

The following tests were performed to demonstrate that the proposed Orchid Safety Release Valve™ met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

Performance Testing

- Usability Testing
- Functional Testing:
  - Tensile Strength Testing (ISO 8536-4 A-3)
  - Air Leakage - Device Not Activated (ISO 80369-20:2015 Annex D)
  - Force to Disconnect
  - Air Leakage - Device Activated (ISO 80369-20:2015 Annex D)
  - Water Leakage - Device Not Activated (ISO 80369-20:2015 Annex C)
  - Water Leakage – Female (ISO 80369-20:2015 Annex C)
  - Water Leakage – Male (ISO 80369-20:2015 Annex C)
  - Flow Rate
  - Re-assembly Prevention
  - Assembly Weight
- Particulate Testing (USP <788>)
- Luer Lock Testing (ISO 80369-7:2016)
- Microbial Ingress Testing
- Clinical Simulation Testing

Sterilization

The Orchis SRV is provided sterile and is sterilized with Ethylene Oxide. The following testing was performed:

- Packaging and Sterilization Testing (ASTM D4169-16, ASTM F88/F88M-15, ASTM F1886/F1886M-16, ATM F2069-11)
- Shelf-Life Testing (ASTM F1980-16)
- Bacterial Endotoxin Testing

The sterilization validation followed the guidelines in the Product Adoption and Process Equivalence for Ethylene Oxide Sterilization AAMI TIR28:2016. The sterilization process has been validated per ISO 14937:2009 using the half dose method. The overkill approach was used to ensure a sterility assurance level (SAL) of 10^{-6} was achieved.

Biocompatibility

Biocompatibility testing was conducted in accordance with the FDA Guidance Document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process," September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The proposed Orchid Safety Release Valve™ is considered an externally communicating, prolonged exposure device that indirectly contacts the blood path. Therefore, the following tests are required:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation/Intracutaneous Reactivity (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)
- Material-Mediated Pyrogenicity (ISO 10993-11:2017)
- Subacute/Subchronic Toxicity (ISO 10993-11:2017)
- Haemocompatibility (ISO 10993-4:2017)

Based on the results of the biocompatibility testing performed on the final Orchid Safety Release Valve™, the SRV meets the requirements outlined in ISO 10993-1:2018.

X. Conclusion

The proposed Orchid Safety Release Valve™ has the same intended use, environment of use, operating principle and fundamental technology, and similar materials as the predicate device. Any differences in the technological characteristics do not raise any new questions or concerns of safety and effectiveness. The information provided in this submission demonstrates that the subject device is substantially equivalent to its predicate.