September 6, 2024

Linear Health Sciences LLC
Jessica Czamanski
Director of Product and Regulatory Affairs
840 Research Parkway
Ste 250
Oklahoma City, Oklahoma 73104

Re: K241415
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: August 9, 2024
Received: August 9, 2024

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 (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,

David Wolloscheck

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241415

Device Name
Orchid Safety Release Valve™

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 SRV™ is intended for use with electronic IV pumps in 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 IV mechanical complications requiring IV replacement.

The Orchid SRV™ is for use with patients two (2) weeks 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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K241415 - 510(k) SUMMARY

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 CEO
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Telephone:	(310) 721-6222
Email:	dan.clark@linearsciences.com
Date Preparation:	September 6, 2024

II. Application Correspondent

Contact's Name:	Linear Health Sciences, LLC
Contact Person:	Jessica Czamanski Director of Product and Regulatory Affairs
Address:	840 Research Parkway, STE 250 Oklahoma City, OK 73104
Telephone:	(754) 422-9101
Email:	jessica.czamanski@linearsciences.com

III. 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:	Linear Health Sciences, LLC
Device Name:	Orchid Safety Release Valve™

510(k) Number:	K232094
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, 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 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 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 IV mechanical complications requiring IV replacement. The Orchid SRV™ is for use with patients two (2) weeks of age and older.

VIII. Comparison of Technological Characteristics with the Predicate Devices

There are no differences in technological characteristics of the device. Only differences are present in the labeling of the Orchid Safety Release Valve, specifically the contraindications to allow for use with blood.

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

Table 1: General Technological Characteristics Comparison

Product Features	**Proposed** Linear Health Sciences' Orchid Safety Release Valve™ (K241415)	**Predicate** Linear Health Sciences' Orchid Safety Release Valve™ (K232094)	**Substantial Equivalence Determination**
Classification	Class II	Class II	Same
Product Code	QOI	QOI	Same
Regulation Number	§880.5220	§880.5220	Same
Device Classification Name	Intravenous Catheter Force-Activated Separation Device	Intravenous Catheter Force-Activated Separation Device	Same
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 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.	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 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.	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 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	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 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	Same

Table 1: General Technological Characteristics Comparison

Product Features	Proposed Linear Health Sciences' Orchid Safety Release Valve™ (K241415)	Predicate Linear Health Sciences' Orchid Safety Release Valve™ (K232094)	Substantial Equivalence Determination
	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 IV mechanical complications requiring IV replacement. The Orchid SRV™ is for use with patients two (2) weeks of age and older.	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 IV mechanical complications requiring IV replacement. The Orchid SRV™ is for use with patients two (2) weeks of age and older.	
Contraindications	The Orchid SRV™ should not be used for any type of fluid administration other than intravenous. Not for use with feeding tubes, drains, or other tubing applications outside of intravenous applications. Not for use in withdrawing blood or fluids. Not for intra-arterial use. Not for use with power injection systems or high-pressure infusion systems. Not for use with umbilical vessel catheters. Not for use under 2 weeks of age. Not for use in line during the transfusion of biologics.	The Orchid SRV™ should not be used for any type of fluid administration other than intravenous. Not for use with feeding tubes, drains, or other tubing applications outside of intravenous applications. Not for use in withdrawing blood or fluids. Not for intra-arterial use. Not for use with power injection systems or high-pressure infusion systems. Not for use with umbilical vessel catheters. Not for use under 2 weeks of age. Not for use in line during the transfusion of blood, blood products, or biologics.	Contraindications have been updated to remove "blood, blood products, or" from the contraindication statements. Blood and blood product use is supported by additional hemocompatibility testing performed on the subject device (refer to Section X below).
Materials	Polycarbonate and silicone	Polycarbonate and silicone	Same
Environment of Use	Hospital	Hospital	Same
Provided Sterile	Yes	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 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	Same

Table 1: General Technological Characteristics Comparison

Product Features	Proposed Linear Health Sciences' Orchid Safety Release Valve™ (K241415)	Predicate Linear Health Sciences' Orchid Safety Release Valve™ (K232094)	Substantial Equivalence Determination
	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 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.	
User Profile	Physician or clinical personnel with clearance to administer IV sets and related products	Physician or clinical personnel with clearance to administer IV sets and related products	Same
Separation Force	1-4.2 lbf	1-4.2 lbf	Same
Vascular Access Catheter Type	Peripheral and Central IV Catheters	Peripheral and Central IV Catheters	Same
For Use with Electronic Pumps	Yes	Yes	Same
Single Use	Yes	Yes	Same
Continuous and Intermittent Infusion	Yes	Yes	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
SAL	10^{-6}	10^{-6}	Same
Shelf-Life	2 years	2 years	Same

IX. Sterilization

There are no differences in the sterilization process between the subject and the predicate device.

X. Performance Data

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

Performance Testing - Bench

There is no change in performance data since there are no changes to the device or its manufacturing processes.

Biocompatibility

To demonstrate the device's safe use with blood and blood products, the following additional hemocompatibility tests were conducted per ISO 10993-4: 2017 *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*: Partial Thromboplastin Time (PTT), Complement Activation, Platelet and Leukocyte Count (PLC) assay, and mechanical hemolysis.

Electrical Safety and Electromagnetic Compatibility (EMC)

There are no electrical or metal components in the proposed Orchid Safety Release Valve™; therefore, the proposed device does not require EMC and Electrical Safety evaluation. Justification of the latter has been included in this submission to support the addition of the MR Safe symbol to the device labeling.

Software Verification and Validation Testing

The Orchid Safety Release Valve™ does not contain software; therefore, the proposed device does not require software verification and validation testing.

Performance Testing - Animal

This submission does not include any animal performance testing. It was determined that no such testing was required to demonstrate substantial equivalence.

XI. Conclusion

The Orchid Safety Release Valve™ has the same intended use, environment, operating principle and fundamental technology, manufacturing, and materials as the predicate device. Additional testing performed to support limited blood contact did not raise new questions for safety or effectiveness. The information provided in this submission demonstrates that the subject device, Orchid Safety Release Valve™ is substantially equivalent to its predicate, Orchid Safety Release Valve™ cleared under K232094.