December 26, 2024

Epic Medical Pte. Ltd.
Freddie Lee
CEO/md
105 Cecil Street #20-04, The Octagon
Singapore, SG 069534
Singapore

Re: K240517
Trade/Device Name: ProSeal™ Vented Universal Vial Adaptor
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: November 25, 2024
Received: November 25, 2024

Dear Freddie Lee:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240517

Device Name
ProSeal™ Vented Universal Vial Adaptor

Indications for Use *(Describe)*
The ProSeal™ Closed System drug Transfer Device (CSTD) mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal™ system also prevents the introduction of microbial contaminations into the drug or fluid path for up to 7 days when used as intended.

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.

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K240517 – 510(k) Summary

I. Submitter

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Contact Person: Mr. Freddie LEE, Chief Executive Officer/ Managing Director
Date Prepared: December 26, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Traditional

II. Subject Device

510(k) Number:	K240517
Trade/ Device Name:	ProSeal™ *Vented Universal Vial Adaptor*
Common/ Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer Device
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

III. Predicate

510(k) Number:	K201422
Trade/ Device Name:	Arisure® *Closed System Drug Transfer Device (CSTD)*
Common/ Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer Device
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

IV. Device Description

This FDA Submission is to include an authorization to legally market the **ProSeal™ *Vented Universal Vial Adaptor*** to the existing ProSeal™ *CSTD* devices system of eleven (11) devices that were cleared for sales in the US, the most recent being the ToxiSeal™ *Vial Adaptor* (K241823).

The ProSeal™ *Vented Universal Vial Adaptor* is a component of the ProSeal™ *CSTD* system intended for connection with the interface membranes between any standard vials and ProSeal™ *CSTD* component devices for close system fluid transfer. When connected to a standard vial and engaged with a ProSeal™ *Injector* (Syringe Adaptor), fluid can be transferred to and from the connecting component device in a closed system. The ProSeal™ *Vented Universal Vial Adaptor* and its corresponding interface membranes exhibit a dry connection with the communicating surfaces in a fluid transfer. The use of this component and its appropriate ProSeal™ *CSTD* component device reduces the risk of microbial ingress for up to 168 hours (or 7 days), when used as intended.

The closed transfer of liquid that takes place with the use of the ProSeal™ *CSTD* system as follows:

- A double membrane septum design utilizing self-sealing elastomeric membranes tightly fits together when the system components engage. A cannula within the ProSeal™ *Injector* housing perforates the double membrane for the transfer of liquid. When the cannula is retracted, the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols, and spills, and also minimizing the risk of microbial contamination.

V. *Indications for Use* Statement

The ProSeal™ Closed System drug Transfer Device (CSTD) mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal™ system also prevents the introduction of microbial contaminations into the drug or fluid path for up to 7 days when used as intended.

VI. Comparison of Technological Characteristics

The ProSeal™ *Vented Universal Vial Adaptor*, a system component of the ProSeal™ *CSTD* and the Predicate, the Arisure® *CSTD's Vial Adaptor*, share the following key characteristics:

- Role of the *CSTD* system component devices
- Residual fluid
- Close system technology/ mechanism of action
- Biocompatibility
- Sterile barrier packaging top web and base web
- Pyrogenicity
- Validated shelf-life

An overview table summarizing the comparison of key characteristics between the Subject ProSeal™ *Vented Universal Vial Adaptor* and the Predicate Arisure® *CSTD's Vial Adaptor* is provided hereunder.

Characteristics compared		Predicate Device (K201422)	Subject Device (K240517)	Comments, discussions
		Arisure® *CSTD - Vial Adaptor*	**ProSeal™ *Vented Universal Vial Adaptor***	
Intended use and *Indications for Use* statement		Arisure® is a Closed System Drug Transfer Device (CSTD) that mechanically prohibits the release of drugs in vapor, aerosol or liquid form during preparation and administration, and prevents the introduction of microbial and airborne contaminants into the drug or fluid path, allowing the system to minimize exposure of individuals, healthcare personnel, and the environment to hazardous drugs.	The ProSeal™ *Closed System drug Transfer Device* (*CSTD)* mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal™ system also prevents the introduction of microbial contaminations into the drug or fluid path for up to 7 days, when used as intended.	Same
Intended user population		Adequately trained health care professionals or pharmacists	Adequately trained health care professionals or pharmacists	Same
Intended use environment		Clinical setting	Clinical setting	Same
Intended drug type		Antineoplastic and hazardous drug	Antineoplastic and hazardous drug	Same
Intended Injector		*Syringe adapter* – a component of the Arisure® *CSTD*	ProSeal™ *Injector* – a component of the ProSeal™ *CSTD* (cleared K192075)	Different See **Comment #1**
Single use or reusable		Single use only	Single use only	Same
Role of the *CSTD* system component devices		Connector (Fluid transfer interface to standard external *vials*) self-sealing elastomeric membrane on all system components	Connector (Fluid transfer interface to standard external vials), self-sealing elastomeric membrane on all system components	Same
Device subcomponents and materials	Injection site protective seal tab	N/A (injection site not present)	Protective seal tab for injection site (PP 348N)	Different See **Comment #1**
	Septum/seal	Flat, split septum of elastomeric membrane – **TPE Medalist 145**	Injection site & its **polyisoprene** membrane (cleared K241823)(fluid path)	Different See **Comment #2**
	Vial adaptor claws	**Acrylonitrile butadiene styrene (ABS), Terlux 2802**	**Polypropylene** (PP, P705JM) integrated whole subcomponent with vial adaptor spike	Different See **Comment #3**
	Vial adaptor spike	**Polycarbonate**	**Polypropylene** (PP, P705JM)(fluid path) integrated whole subcomponent with vial adaptor claws	
	Filter	PTFE membrane, **0.2 micron**	PTFE membrane, **0.1 micron**	Different See **Comment #4**

Characteristics compared	Predicate Device (K201422) **Arisure® *CSTD - Vial Adaptor***	Subject Device (K240517) **ProSeal™ *Vented Universal Vial Adaptor***	Comments, discussions
Device dimensions	External dimensions (L×W) mm (inch): • Vial adapter: 63.50 × 57.15 (2.5 × 2.25) • Vial spike: 101.40 × 12.70 (4.0 × 0.5)	External dimensions (L×W) mm (inch): • Vial adaptor claws: 34.4 × 34.0 (1.4 × 1.3) • Total L×W: 54.4 × 34.0 (2.1 × 1.3)	Different See **Comment #1**
Residual fluid	<0.05 mL for 13 mm & 20 mm <1 mL for 28 mm	<0.05 mL	Same
Drug vial interface	Arisure™ *Vial Adaptor* snap lock and elastomeric membrane – **TPE Medalist 145**	ProSeal™ *Vented Universal Vial Adaptor*: snap lock and elastomeric membrane - **polyisoprene**	Different See **Comment #2**
Closed system technology/ mechanism of action	Physical barrier to prevent all mass from crossing the system boundary	Physical barrier to prevent all mass from crossing the system boundary	Same
Design configuration and function of drug vial perforator	Arisure™ *Vial Adaptor*: plastics, **ABS Terlux 2802 vial adaptor claws and polycarbonate vial adapter spike** Predicate vial adaptor incorporates the *Universal vial spike* - a dual lumen spike - that makes for smooth fluid transfers while it minimizes the drug residue left in the vial. When used with the Arisure™ *Syringe Adaptor*, the system provides transfer of compounds safely and efficiently while maintaining a closed system	ProSeal™ *Vented Universal Vial Adaptor*: plastic, **polypropylene integrated vial adaptor claws and vial adaptor spike** Subject vial adaptor incorporates the *Universal vial spike* - a dual lumen spike - that makes for smooth fluid transfers while it minimizes the drug residue left in the vial. When used with the ProSeal™ *Injector*, the system provides transfer of compounds safely and efficiently while maintaining a closed system	Different See **Comment #3**
Pressure equalization in drug vial	Integrated PTFE air-vent for air equalization into and out of the drug vial Predicate vented adaptor incorporates a venting mechanism incorporating a **0.2 micron** air filter that minimizes aerosols and surface contamination and allows for the release of pressure, thus neutralizing vial pressure during drug transfer The venting mechanism enables pressure equalization within the vial, reducing the risk of vial collapse or spray-back during drug withdrawal, while maintaining a closed system	Integrated PTFE air-vent for air equalization into and out of the drug vial Subject vented adaptor incorporates a venting mechanism incorporating a **0.1 micron** air filter that minimizes aerosols and surface contamination and allows for the release of pressure, thus neutralizing vial pressure during drug transfer The venting mechanism enables pressure equalization within the vial, reducing the risk of vial collapse or spray-back during drug withdrawal, while maintaining a closed system	Different See **Comment #4**

Characteristics compared	Predicate Device (K201422) Arisure® *CSTD - Vial Adaptor*	Subject Device (K240517) ProSeal™ *Vented Universal Vial Adaptor*	Comments, discussions
Biocompatibility	Externally Communicating Device, Blood Path Indirect, Prolonged Contact (>24hr to 30d)	Externally Communicating Device, Blood Path Indirect, Prolonged Contact (>24hr to 30d)	Same
Sterile barrier packaging top web and base web	Medical grade paper and medical plastic film, heat sealed. Form, fill, seal packaging with top web material sealed to bottom web material	Medical grade paper and medical plastic film, heat sealed. Form, fill, seal packaging with top web material sealed to bottom web material	Same
Sterilization process	Gamma Irradiation, SAL 10^{-6}	Ethylene Oxide (EO), SAL 10^{-6}	Different See **Comment #5**
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
Prescription use or over-the-counter use	℞ only	℞ only	Same
Shelf-life validation	36 months	36 months	Same

Discussion of differences in technological characteristics

Comment #1

Differences in subcomponents (noted in ***Comments #1 to #4***) related to their subcomponent types, dimensions and materials, as well as the different intended injectors, are considered, noting that all these aspects achieve the same intended use. Key differences in materials are addressed individually in ***Comment #2*** and ***Comment #3***, and difference in air-vent size, in ***Comment #4***. Biocompatibility evaluations and functional performance testing demonstrate that all the differences do not raise new questions regarding safety and effectiveness.

Comment #2

Polyisoprene vs. TPE: The Subject device's elastomeric membrane is made of the same **polyisoprene** as cleared K241823 ToxiSeal™ *Vial Adaptor* subcomponent membrane. Biocompatibility and performance testing demonstrate that the difference does not raise new questions regarding safety and effectiveness.

Comment #3

Polypropylene vs. ABS Terlux 2802 & polycarbonate: The Subject device's vial spike material is made of the same polypropylene as cleared K241823 ToxiSeal™ *Vial Adaptor's* subcomponent vial adaptor spike. Biocompatibility evaluation and performance testing demonstrate that the difference does not raise new questions regarding safety and effectiveness.

Comment #4

0.1 micron air-vent vs. 0.2 micron air-vent: The difference in **0.1 micron air-vent** in Subject device vs **0.2 micron air-vent** in Predicate device is noted. The cleared ToxiSeal™ *Vial Adaptor* incorporates the same air-vent (0.1 micron) (K241823). Performance testing demonstrates that this difference does not raise new questions regarding safety and effectiveness.

Comment #5

EO sterilization vs. gamma sterilization: Use of gamma versus EO processes does not raise any new questions regarding safety and effectiveness. Both are assured to the same SAL as demonstrated by adequate sterility testing.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The ProSeal™ *Vented Universal Vial Adaptor* described in this Summary were tested and demonstrated to be in conformance with the following ISO and FDA recognized standards:

- ISO 8871-5:2016, *Elastomeric parts for parenterals and for devices for pharmaceutical use Part 5: Functional requirements and testing*
- ISO 8536-2:2010, *Infusion equipment for medical use – Part 2: Closures for infusion bottles*
- ISO 8536-4:2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 22413:2010, *Transfer sets for pharmaceutical preparations – Requirements and test methods*
- *Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)]---Guidance-for-Industry-and-FDA-Staff*
- NIOSH 2016, *Performance Test (draft) Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*

Bench performance verifications and validations performed on the Subject device and cleared device:

- Positive and negative air pressure leakage test to ISO 8536-4:2019
- Positive pressure water leak integrity test to ISO 8536-4:2019
- Penetration force test of vial perforator to ISO 22413:2021
- Fragmentation test to ISO 22413:2021 and to ISO 8871-5:2016
- Vapor containment test per NIOSH CSTD 2016 draft test protocol (functional) from testing data on devices cleared under K241823
- Microbial ingress test per FDA guidance, ANSI AAMI CN27:2021 and ISO 80369-7:2021 (functional) from testing data on device cleared under K222929

B. Biocompatibility

In accordance with ISO 10993-1:2018, the ProSeal™ *Vented Universal Vial Adaptor* is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing are referenced from testing on cleared devices of ProSeal™ *CSTD*:

- Cytotoxicity to ISO 10993-5 under K192075
- Sensitization to ISO 10993-10 under K192075
- Intracutaneous Reactivity to ISO 10993-10 under K192075
- Acute Systemic Toxicity to ISO 10993-11 under K192075
- 14-day Subacute/ Subchronic Acute Systemic Toxicity to ISO 10993-11 under K222929
- In-vitro Hemolysis Assessment to ISO 10993-4 under K192075 and K192075/S001
- Material Mediated Pyrogenicity to ISO 10993-11 under K192075
- Chemical Characterization and Toxicological Risk Management to ISO 10993-18 and ISO 10993-17 under K192075/S001 and K222929

Particulate matter testing was conducted on the Subject device, in accordance with ISO 8536-4:2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed, Annex A.2* and USP <788> *Particulate Matter in Injections*.

C. Sterility, Shipping, and Shelf-Life

The Subject device complies with sterilization requirements of ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices* and the following testing/ evaluations:

- Simulated shipping testing per ASTM D4169-16, *Standard Practice for Performance Testing of Shipping Containers and System* under K192075
- Package Integrity Tests per ASTM F1980-16, *Standard guide for accelerated aging of sterile barrier systems for medical devices and* Sterile Barrier Packaging Testing performed on the proposed device: Seal strength – ASTM F88/F88M-21, *Standard test method for seal strength of flexible barrier materials,* ASTM F1929-15, *Standard test method for detecting seal leaks in porous medical device packaging by dye penetratio*n, EN 868-5:2018, *Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods*
- Pyrogen Tests per ANSI/AAMI ST72/2019, *Bacterial endotoxins – Test methods, routing monitoring,* and *alternatives to batch testing,* USP 40 <151>, *Pyrogen test (USP rabbit test),* USP-NF <161>, *Medical Devices-Bacterial Endotoxin and Pyrogen Tests,* USP-NF <85>, *Bacterial Endotoxins Test* and testing will be conducted on every lot
- Shelf-life of 3 years has been validated using the FDA recognized standard, ASTM 1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

VIII. Clinical Tests

Not applicable.

IX. Conclusion

The differences between the Predicate and the Subject device do not raise any new or different questions of safety or effectiveness. The **ProSeal™** ***Vented Universal Vial Adaptor*** is substantially equivalent to the Predicate, the **Arisure™** ***CSTD - Vial Adaptor***, cleared under **K201422** with respect to the indications for use, principles of operation and technological characteristics.