October 23, 2024

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

Re: K241988
Trade/Device Name: ProSeal™ Closed System Bag Access
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: September 23, 2024
Received: September 23, 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
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)*
K241988

Device Name
ProSeal™ Closed System Bag Access

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.

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

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K241988 – 510(k) Summary

I. Submitter

Epic Medical Pte. Ltd.
105 Cecil Street #20-04,
The Octagon,
Singapore 069534.
Phone: +65 9635 2618 / +66 81 761 5292
Contact Person: Mr. Freddie LEE, Chief Executive Officer/ Managing Director
Date Prepared: October 23, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Traditional

II. Subject Device

510(k) Number:	K241988
Trade/ Device Name:	ProSeal™ *Closed System Bag Access*
Common/ Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

III. Predicate

510(k) Number:	K201460
Trade/ Device Name:	Closed System Transfer Device
Common/ Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

IV. Device Description

The ProSeal™ *CSTD* is a sterile, single-use, pyrogen-free *CSTD* for the preparation, reconstitution, compounding, and administration of antineoplastic and hazardous drugs, intended for use in clinical settings by trained health care professionals and/or pharmacists.

The ProSeal™ *Closed System Bag Access* is a component of the ProSeal™ *CSTD* system which is intended for connection to a standard I.V. bag and appropriate ProSeal™ *CSTD* component devices for the injection and infusion of I.V. infusion fluids. It is an adaptor between IV bags and ProSeal™ *CSTD* components for closed system fluid transfer into and out of the I.V. bag. The Subject bag access is compatible with the ProSeal™ *Injector* or the ProSeal™ *Injector Plus* (cleared K240171) and other ProSeal™ component devices, e.g. ProSeal™ *Closed System Administration Set* (for infusion from the I.V. bag). The ProSeal™ *Closed System Bag Access* and all its corresponding interface membranes exhibit a dry connection with the communicating surfaces in a fluid transfer. The use of this component device and its appropriate ProSeal *CSTD* connecting 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* or *Injector Plus* housing perforates the double membranes 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, when used as intended.

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 Intended Use & Technological Characteristics

The Subject device and the Predicate device share the following similar characteristics:

Intended Use comparison

1) *Indications for use* statements
2) Primary product code and regulation number
3) Intended user population/ intended use environment
4) Intended drug type
5) Single use or reusable, single patient use

Technological characteristics comparison

Equivalencies – Technology & Design

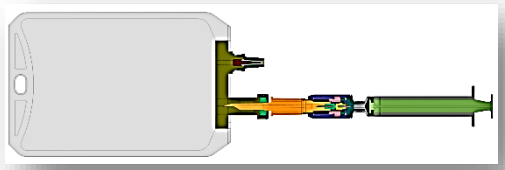
The *ProSeal™ Closed System Bag Access* and the Predicate device share the following similar design characteristics, and from the evaluation in the comparison table, there was no substantial difference from the Predicate device identified, that would raise a different question of safety or effectiveness:

1) Principles of operation
2) Number of access points
3) Intended connector type to be used with the bag spike adapter
4) Safety feature to prevent microbial contamination
5) Sterile barrier packaging
6) Sterilization process
7) Shelf-life

An overview table summarizing the comparison between the key characteristics between the Subject and the Predicate device is provided hereunder.

Characteristic compared	**Predicate Device** (K201460) *CSTD - Spike Adapter*	**Subject Device** (K241988) ProSeal™ *Closed System Bag Access*	**Comment/ Discussion**
Intended use and *Indications for Use* statement	"The *Closed System Transfer Device (CSTD)* for preparation, reconstitution, compounding and administration of drugs, including antineoplastic and hazardous drugs. This closed system mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills and also prevents microbial ingress."	"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."	Similar

Characteristic compared	**Predicate Device** (K201460) *CSTD - Spike Adapter*	**Subject Device** (K241988) ProSeal™ *Closed System Bag Access*	**Comment/ Discussion**
Primary product code and regulation number	ONB 21 CFR 880.5440	ONB 21 CFR 880.5440	Same
Intended user population/ intended use environment	Adequately trained health care professionals including pharmacists/ clinical setting	Adequately trained health care professionals including pharmacists/ clinical setting	Same
Intended drug type	Parenteral drugs	Parenteral drugs	Same
Single use or reusable	Single use only	Single use only	Same
Principles of operation	Infusion bag is connected with spike adapter, then in order to realize the connection between infusion bag and spike adaptor, they are connected with the matching end of the dispensing connector. All system components are sealed with resealing membranes, and elastomeric double membrane technology is used to ensure that there is no drug leakage at the connecting parts during the dispensing process. As closed Infusion Set, the working principle of the infusion set is gravity infusion, which is connected with the indwelling needle or other connector(s). Under the action of gravity, the medicine is infused into human blood vessels through the infusion tube.	The infusion bag is connected with the bag access and, in order to create a fluid path connection between the infusion bag and the bag access, they are connected with the matching end of the ProSeal *Injector* or *Injector Plus* (K240171). All system components are sealed with self-resealing membranes incorporating elastomeric double membrane technology that features airtight and leakage-proof connections during the fluid transfer process. Transfer is performed through the connection of an I.V. set with indwelling needle of the ProSeal *Injector* (or *Injector Plus*) connector, e.g. the ProSeal *Closed System Administration Set* (cleared K230343), into the human veins.	Same
Components	• Vial Adapter • Spike Adapter • Dispensing Connector • Closed Infusion Set	• Spike Adapter	Different, See **Comment #1**

Characteristic compared	**Predicate Device** (K201460) *CSTD - Spike Adapter*	**Subject Device** (K241988) ProSeal™ *Closed System Bag Access*	**Comment/ Discussion**
Number of access points	Device has 2 access points: 1. Closed system port 2. Spiking/ administration port, IV spike bag access	Device has 2 access points: 1. Closed system port 2. Spiking/ administration port, IV spike bag access	Same
Composition of fluid path materials	ABS (spike), synthetic rubber (sealing element/ membrane/ septum)	Polypropylene (PP) (spike), polyisoprene (IR) (sealing element/ membrane/ septum)	Different, See **Comment #2**
Intended connector type to be used with the bag spike adapter	 Shiva Ande Healthcare Apparatus manufacturer's dedicated *Dispensing Connector* (K201460) male Luer lock tip, connected to an external standard MLL syringe	 Epic Medical Pte Ltd manufacturer's cleared ProSeal™ *Injector* or *Injector Plus* (K240433) male Luer lock tip, connected to an *external* standard MLL syringe	Same
Safety feature to prevent microbial contamination	Leak proof connector with membranes (septums) seal – elastomeric resealing double membrane	Airtight and leakage-proof adaptor with membranes (septums) seal – elastomeric resealing double membrane – closed system technology	Same
Sterile barrier packaging	Medical grade paper and medical plastic film, heat sealed	Medical grade paper and medical plastic film, heat sealed	Same
Sterilization process	Ethylene Oxide (EO), SAL 10^{-6}	Ethylene Oxide (EO), SAL 10^{-6}	Same
Shelf-life validation	3 years (36 months)	3 years (36 months)	Same

Discussion of difference in technological characteristics

Comment #1

Submission K241988 is to include an authorization of the ProSeal™ *Closed System Vial Access*, a single component device, to the existing ProSeal™ *CSTD* system of 11 component devices (K241823). Compared to Predicate K201460, the application was for 4 component devices. The difference does not raise different questions of safety and effectiveness as the Subject device contains a subset of the Predicate device component devices. Bench top, biocompatibility, and sterility data demonstrate the difference does not raise different questions in safety and effectiveness as described in section VII.

Comment #2

Though the Subject device's bag spike and membrane material differ with the Predicate, both the PP and IR materials are the same in type, make, grade and manufacturer source as those used in the cleared ToxiSeal™ *Vial Adaptor with External Balloon* (K222929) that have been tested to demonstrate biocompatibility. In addition, performance testing demonstrates the difference in material does not raise different questions of safety and effectiveness.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The Subject device in this Summary was evaluated to be in conformance with the following ISO and FDA recognized standards and FDA guidance document:

- ANSI AAMI CN27:2021, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*
- ISO 8536-4: 019, *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*

Bench performance verifications and validations referred-to and performed:

- Leak integrity test (functional) – per ISO 8536-4:2019, paragraph 7.2 and Annex A.3, performed on Subject devices
- Tensile strength test (functional) – per ISO 8536-4:2019, paragraph 7.3 and Annex A.4, performed on Subject devices
- Penetration force test (functional) – per ISO 22413:2021, Section 6.6, Annex A.7, performed on Subject devices
- Protective caps test (functional) – per ISO 8536-4:2019, Section 7.13, performed on Subject devices
- Vapor containment test per NIOSH CSTD 2016 draft test protocol (functional) from testing data on devices cleared under K222929
- Microbial ingress test per FDA guidance and ANSI AAMI CN27:2021 (functional) from testing data on devices cleared under K222929

B. Biocompatibility

In accordance with ISO 10993-1: 2018, the Subject device just like the existing ProSeal™ *CSTD* devices, is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were performed on referred-to cleared devices:

- Cytotoxicity to ISO 10993-5 under K222929
- Sensitization to ISO 10993-10 under K222929
- Intracutaneous Reactivity to ISO 10993-10 under K222929
- Acute Systemic Toxicity to ISO 10993-11 under K222929
- 14-day Subacute/ Subchronic Acute Systemic Toxicity to ISO 10993-11 under K222929
- In-vitro Hemolysis Assessment to ISO 10993-4 under K222929
- Material Mediated Pyrogenicity to ISO 10993-11 under 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* 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 conducted devices cleared under K222929:

- Simulated shipping testing per ASTM D 4169-16*, Standard Practice for Performance Testing of Shipping Containers and Systems*
- Package Integrity Tests per ASTM F1980-21, *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*; Dye Penetration – ASTM F1929-23, *Standard test method for detecting seal leaks in porous medical device packaging by dye penetratio*n; EN 868-5:2009, *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 1980-21, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*.

VIII. Clinical Tests

Not applicable.

IX. Conclusion

The difference between the Predicate and the Subject device does not raise any new or different questions of safety or effectiveness. The Subject device – **ProSeal™ *Closed System Bag Access*** – is substantially equivalent to the Predicate device, ***CSTD-Spike Adapter*** (manufactured by Shinva Ande Healthcare Apparatus Co., Ltd.), (K201460) – with respect to its indications for use, principles of operation and technological characteristics.