May 29, 2025

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

Re: K251340
Trade/Device Name: ProSeal™ Bag Spike with Additive Port (423370ST, 423370)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: April 30, 2025
Received: April 30, 2025

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,

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)*
K251340

Device Name
ProSeal™ Bag Spike with Additive Port (423370ST, 423370)

Indications for Use *(Describe)*
The ProSeal™ 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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K251340 – 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: May 26, 2025
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K251340
Trade/ Device Name:	ProSeal™ *Bag Spike with Additive Port* (423370ST, 423370)
Common/ Usual Name:	*Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System*
Regulation Number:	Set, Administration, Intravascular
Regulation Name:	21 CFR 880.5440
Regulatory Class:	Class: II
Product Code:	ONB

III. Predicate

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:	Set, Administration, Intravascular
Regulation Name:	21 CFR 880.5440
Regulatory Class:	Class: II
Product Code:	ONB

IV. Purpose of Submission and Device Description

This special 510(k) Submission is to comply with FDA requirements, ensuring the **ProSeal™ *Bag Spike with Additive Port (*or "*and Seal Tab")*** is safe and effective for use in closed system fluid transfer applications.

The **ProSeal™ *Bag Spike with Additive Port (*or "*and Seal Tab"*** *(suffixed ST model no.))* serves as an adaptor between I.V. bags and ProSeal™ *CSTD* components, facilitating closed system fluid transfer. The *spiking port* of this device is compatible with generic I.V. spikes. Additionally, the additive port *(injection site)* allows medication to be added to the bag using the cleared ProSeal™ *Injector* or *Injector Plus* (both Syringe Adaptors).

The *injection site* of the **ProSeal™ *Bag Spike with Additive Port (*or "*and Seal Tab")*** and all corresponding interface membranes ensure a dry connection during fluid transfer. Utilizing this component and its appropriate ProSeal™ *CSTD* connecting component reduces the risk of microbial ingress for up to 168 hours (7 days).

V. *Indications for Use* Statement

The ProSeal™ *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 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) Prescription use or over-the-counter use

Technological characteristics comparison

Equivalencies – Technology & Design

The Subject device and the Predicate device share the following design characteristics, and from the evaluation in the comparison table, there was no substantial difference from the Predicate device identified, that would raise a safety or performance issue/ concern:

1) Connection between component devices within the *CSTD* system
2) Transfer mechanism (role: to facilitate airtight & leak-proof connections to prevent microbial contamination)
3) Sterile barrier packaging
4) Sterilization process
5) Shelf-life validation
6) Reuse or single-use
7) Labeling specifications

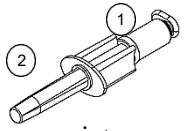
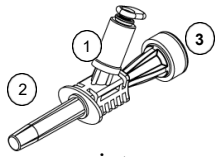
Comparison of intended use characteristics and the technological characteristics

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

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K241988) **ProSeal™ *Closed System Bag Access***	**Subject Device** (K251340) **ProSeal™ *Bag Spike with Additive Port***	**Comment/ Discussion**
Intended use and *Indications for Use* statement	The ProSeal™ *CSTD* system 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 contaminants into the drug or fluid path for up to 7 days when used as intended.	The ProSeal™ *CSTD* system 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 contaminants into the drug or fluid path for up to 7 days when used as intended.	Same
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/ clinical setting	Adequately trained health care professionals/ clinical setting	Same
Intended drug type	Parenteral drugs	Parenteral drugs	Same
Prescription use or over-the-counter use	℞ only	℞ only	Same

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K241988) **ProSeal™ *Closed System Bag Access***	**Subject Device** (K251340) **ProSeal™ *Bag Spike with Additive Port***	**Comment/ Discussion**
Principles of operation	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 an indwelling needle of the ProSeal *Injector* (or *Injector Plus*) connector, **e.g. the ProSeal *Closed System Administration Set* (cleared K230343), into the human veins.**	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 an indwelling needle of the ProSeal *Injector* (or Injector Plus) connector. **The *spiking port* of the ProSeal™ *Bag Spike with Additive Port* (or *and Seal Tab (suffixed ST model))* is compatible with generic I.V. spikes connected to I.V. Administration Sets for dispensing into the human veins.**	Different see **Comment #1**
Number of access points	 Device has 2 access points: 1. Closed system port *(injection site)* 2. Spike port, I.V. *(bag spike (integrated with injection site MLL))*	 Device has 3 access points: 1. Closed system port *(injection site)* 2. Spike port, I.V. *(bag spike (integrated with injection site MLL **& spiking/ administration port**))* 3. ***Spiking port stopper***	Different see **Comment #1**

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K241988) **ProSeal™ *Closed System Bag Access***	**Subject Device** (K251340) **ProSeal™ *Bag Spike with Additive Port***	**Comment/ Discussion**
Composition of fluid path materials	• Polyisoprene (IR) *(membrane of injection site)* • Polypropylene (PP) *(spike port, I.V.)*	• Polyisoprene (IR) *(membrane of injection site)* • Polypropylene (PP) *(spike port, I.V.)* • **Thermoplastic elastomer (TPE) *(spiking port stopper)***	Different see **Comment #2**
Connection between component devices within the *CSTD* system	Collet-style fitting with elastomeric double membranes	Collet-style fitting with elastomeric double membranes	Same
Transfer mechanism (role: to facilitate airtight & leak-proof connections to prevent microbial contamination)	Elastomeric double membrane	Elastomeric double membrane	Same
Biocompatibility	Acceptable biological risks established	Acceptable biological risks established	Same see **Comments #2**
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
Reuse or single-use	Single use only	Single use only	Same
Labeling specifications	Met the requirements specified in 21 CFR 801	Met the requirements specified in 21 CFR 801	Same

Submitter's Comments

Comment #1

Subject devices are different from the Predicate device in having a **third access point – the spiking port (with its TPE stopper)** for connection to standard I.V. spikes of I.V. Administration Sets. The differences between the Subject devices and Predicate device did not raise different questions of safety and effectiveness as functional and analytical testing have been conducted and data evaluated. These data are summarized in **section VII.A**, and **section VII.B** of this 510(k) Summary, and in **Comment #2** hereunder. The differences were determined to be insignificant as performance results were determined to have met the intended use

Comment #2

Subject device's *spiking port stopper* is same subcomponent part (made of the same material and of the same configuration) used in the cleared K223674 eZSURE™ *Empty Fluid Container's spiking port stopper*

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 standards document:

- **ANSI AAMI CN27:2021**, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*
- **ISO 8536-4: 2019**, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- **ISO 15747: 2018**, *Plastic containers for intravenous injections*
- **ISO 22413:2010**, *Transfer sets for pharmaceutical preparations — Requirements and test methods*
- **ISO 80369-7: 2016**, *Small-bore connectors for liquids and gases in healthcare application - Part 7, Connectors for intravascular or hypodermic applications*
- ***Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)]---Guidance-for-Industry-and-FDA-Staff***

Bench performance verifications and validations performed on the Subject device and referred-to from existing devices **(**K222929 (data of *isoprene membrane* in cleared *Injection Site w/Extended MLL* (K240433), the same *membrane* part used in Predicate K241988) and K223674**)**:

- **Leak integrity test** (functional) – per ISO 8536-4:2019, paragraph 7.2 and Annex A.3, performed on Subject device
- **Tensile strength test** (functional) – per ISO 8536-4:2019, paragraph 7.3 and Annex A.4, performed on Subject device
- **Flow rate test** (functional) – per ISO 8536-4:2019, Annex A.5.1 performed on Subject device
- **Protective caps test** (functional) – per ISO 8536-4:2019, Section 7.13, performed on Subject device
- **IV Bag Spike penetration force test** (functional) – per ISO 22413:2021, Annex A.7 on Subject device
- **Spiking port penetration ability** (functional) on device cleared under K223674
- **Spiking port adhesion strength** (functional) on device cleared under K223674
- **Impermeability to microorganism** (Annex C.2 ISO 15747:2018)(functional) on device cleared under K223674
- **Vapor containment test** per NIOSH CSTD 2016 draft test protocol (functional) from testing data on device cleared under K222929
- **Microbial ingress test** per FDA guidance and ANSI AAMI CN27:2021 (functional – 7-days) from testing data on devices cleared under K222929 and K223674

B. Biocompatibility

In accordance with ISO 10993-1:2018, the Subject device is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were conducted on the existing 510(k) cleared referred-to devices (K222929 (data of *isoprene membrane* in cleared *Injection Site w/Extended MLL* (K240433)), K223674 (data of *polypropylene 2-port sub-assembly for IV bag,* as well as for *TPE spiking port stopper*) and Predicate K241988):

- **Cytotoxicity** to ISO 10993-5 performed on devices cleared under K222929 and K223674
- **Sensitization** to ISO 10993-10 performed on devices cleared under K222929 and K223674
- **Intracutaneous reactivity** to ISO 10993-10 performed on devices cleared under K222929 and K223674
- **Acute systemic toxicity** to ISO 10993-11 performed on devices cleared under K222929 and K223674

- **14-day subacute/subchronic systemic toxicity** to ISO 10993-11 performed on devices cleared under K222929 and K223674
- **In-vitro hemolysis assessment** to ISO 10993-4 performed on device cleared under K222929 and K223674
- **Material mediated pyrogenicity** to ISO 10993-11 performed on devices cleared under **K222929 and K223674**
- **Chemical characterization and toxicological risk management** to ISO 10993-18 and ISO 10993-17 on device cleared under Predicate K241988 (leveraging data of *polypropylene spike port, I.V.* as well as for *isoprene membrane*)
- **Chemical requirements testing** to ISO15747:2018, Annex B – Chemical requirements performed on device cleared under K223674
- **Particulate matter analysis** to 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* were conducted on devices cleared under K223674 Predicate K241988

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 D 4169-16*, Standard Practice for Performance Testing of Shipping Containers and Systems* (leveraging data under K151650)
- **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* on Subject device
- **Pyrogen tests** per ANSI/AAMI ST72/2019, *Bacterial endotoxins – Test methods, routing monitoring,* and *alternatives to batch testing,* USP 42-NF 37 <151>, *Pyrogen test (USP rabbit test),* USP 42-NF 37 <161>, *Medical Devices-Bacterial Endotoxin and Pyrogen Tests,* USP 42- NF 37 <85>, *Bacterial Endotoxins Test* under K151650 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* on Subject device

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 ProSeal™ *Bag Spike with Additive Port* (K251340)** is substantially equivalent to the **Predicate, ProSeal™ *Close System Bag Access* (K241988)**, with respect to the indications for use, principles of operation and technological characteristics