December 5, 2025

Epic Medical Pte. Ltd.
Freddie Lee
Chief Executive Officer/Managing Director
105 Cecil Street #20-04, The Octagon
Singapore, SG 069534
Singapore

Re: K251722
Trade/Device Name: ProSeal™ Transfer Injector (421120, 421130, 421140)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: November 6, 2025
Received: November 6, 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 -S

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)*
K251722

Device Name
ProSeal™ Transfer Injector

Indications for Use *(Describe)*
The ProSeal™ Transfer Injector is a component of the ProSeal™ Closed System drug Transfer Device (CSTD) system. 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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K251722 – 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: December 2, 2025
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K251722
Trade/ Device Name:	ProSeal™ *Transfer Injector* (421120, 421130, 421140)
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:	K240171
Trade/ Device Name:	ProSeal™ *Injector Plus (Model no. 421050)*
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

The **ProSeal™ *Transfer Injector***, the Subject device in this Submission, is a modified series of ProSeal™ *Injector Plus*, adding to the existing *Injector* (cleared K240171). The addition further enhances the completeness of the portfolio of Epic Medical Pte. Ltd.'s ProSeal™ *Injectors*.

The **ProSeal™ *Transfer Injector*** is a fully encapsulated syringe unit that that supports the use of ProSeal™ *Injector Plus* (K240171) in hazardous drug handling. The integrated ProSeal™ *Injector Plus* which incorporates a female connector, is permanently attached onto the syringe body, thus preventing accidental disconnections. It houses a shielded needle to prevent the risk of accidental needle sticks. All **ProSeal™ *Transfer Injector*** subcomponents are not made with DEHP*, latex nor BPA and substantiated for safe use with antineoplastic and hazardous drugs.

*DEHP – Di (2-ethylhexyl) phthalate (DEHP), a plasticizer to make PVC soft and flexible. It *is a substance known to cause cancer or reproductive toxicity.*

V. *Indications for Use* Statement

The ProSeal™ *Transfer Injector* is a component of the ProSeal™ *Closed System drug Transfer Device (CSTD)* system. 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:

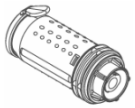
1) Needle-stick injury protection
2) Connection between component devices within the CSTD system
3) Transfer mechanism (role: to facilitate airtight & leak-proof connections)
4) Particulate contamination level
5) Sterile barrier packaging
6) Sterilization process
7) Shelf-life validation
8) Reuse or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

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** (K240171) **ProSeal™ *Injector Plus***	**Subject Device** (K251722) **ProSeal™ *Transfer Injector***	**Comment/ Discussion**
Intended use and *Indications for Use* statement	**The ProSeal™ *Injector Plus* is a component device within the ProSeal™ *CSTD***. 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 **168 hours** or 7 days, when used as intended.	**The ProSeal™ *Transfer Injector* is a component device within the ProSeal™ *CSTD***. 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.	Similar
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
Device construction & composition of fluid-path / -contacting materials	*Injector Plus* housing – Polyoxymethylene (POM) (with female Luer lock hub guard)	*Injector Plus* housing – Polyoxymethylene (POM) (with female Luer lock hub guard)	Same
	Injector cap – Thermoplastic elastomer (TPE)	*Injector* cap – Thermoplastic elastomer (TPE)	Same

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K240171) **ProSeal™ *Injector Plus***	**Subject Device** (K251722) **ProSeal™ *Transfer Injector***	Comment/ Discussion
	Needle hub retainer –Polycarbonate (PC)	Needle hub retainer –Polycarbonate (PC)	Same
	Needle hub Luer thread sub-assembly a. Needle hub FLL – Polypropylene (PP) b. Cannula – Stainless steel SUS 304	Needle hub Luer thread sub-assembly c. Needle hub FLL – Polypropylene (PP) d. Cannula – Stainless steel SUS 304	Same
	Retainer ring for membrane – Acrylonitrile butadiene styrene (ABS)	Retainer ring for membrane – Acrylonitrile butadiene styrene (ABS)	Same
	Membrane – Thermoplastic Elastomer (TPE)	Membrane – Thermoplastic Elastomer (TPE)	Same
	Gripper clamp – Acrylonitrile butadiene styrene (ABS)	Gripper clamp – Acrylonitrile butadiene styrene (ABS)	Same
	Shuttle housing – Polypropylene (PP)	Shuttle housing – Polypropylene (PP)	Same
	 Syringe not present	 ProSeal™ *Injector Plus* integrated with syringe, consisting of syringe barrel, plunger and plunger stopper	Different, see **Comment #1**
Needle-stick injury protection	Needle is inherently inaccessible to user whether engaged or disengaged	Needle is inherently inaccessible to user whether engaged or disengaged	Same

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K240171) **ProSeal™ *Injector Plus***	**Subject Device** (K251722) **ProSeal™ *Transfer Injector***	Comment/ Discussion
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)	Elastomeric double membrane	Elastomeric double membrane	Same
Injector connection to external standard syringe	Luer Lock connector	Lock force-fit attached to its integrated syringe subassembly by rotating Luer-lock connector/syringe lock-ring	Different, see **Comment #1**
Particulate contamination level	Met contamination index on **Predicate device**, N≤90 according to ISO 8536-4, *Infusion Equipment for Medical Use, Part 4: Infusion sets for single use, gravity feed, Annex A, A.2 - Test for particulate contamination* and USP <788> *Particulate Matter in Injection*s	Met contamination index on **Subject device**, N≤90 according to ISO 8536-4, *Infusion Equipment for Medical Use, Part 4: Infusion sets for single use, gravity feed, Annex A, A.2 - Test for particulate contamination* and USP <788> *Particulate Matter in Injection*s	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
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 an attached hypodermic syringe without needle. The differences between the Subject devices and Predicate device did not raise different questions of safety and effectiveness as analytical and functional testing have been conducted (and evaluated) and their data are summarized in section VII.A of this 510(k) Summary. The differences were determined to be insignificant as performance results were determined to have met the intended use

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:

- **ISO 7864:2016***, Sterile hypodermic needles for single use – Requirements and test methods.*
- **ISO 7886-1:2017***, Sterile hypodermic syringes for single use – Part 1: Syringes for manual use*
- **ISO 8536-4: 2019**, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- **ISO 23908: 2011**, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*
- **ISO 80369-7: 2016**, *Small-bore connectors for liquids and gases in healthcare application - Part 7, Connectors for intravascular or hypodermic applications*

Bench performance verifications and validations were performed on the Subject device and referred-to existing device

Referenced from existing Predicate device (K240171)

- **Positive pressure fluid leakage test**
- **Sub-atmospheric pressure air leakage test**
- **Stress cracking test**
- **Resistance to separation from axial load test**
- **Resistance to separation from unscrewing test**
- **Resistance to overriding**
- **Drop test**
- **Flexural force test**
- **Tensile force test**
- **Compression force test**
- **Testing access to the sharp in safe mode**
- **Device leakage integrity test**
- **Needle bonding strength**
- **Sharps injury protection test**

Performed on Subject device (K251722)

- **Tolerance on graduated capacity tests**, in accordance with ISO 7886-1:2017, Table 1
- **Design test of plunger stopper**, in accordance with ISO 7886-1:2017, Annex B
- **Determination of dead space test**, in accordance with ISO 7886-1:2017, Annex C
- **Air and liquid leakage past syringe plunge stopper test**, in accordance with ISO 7886-1:2017, Annex D
- **Force needed to operate the piston test**, in accordance with ISO 7886-1:2017, Annex E, Table E
- **Fit of plunger stopper test**, in accordance with ISO 7886-1:2017, Clause 13.4
- **Leak integrity tests**, in accordance with ISO 8536-4:2019, Annex A.3.2, A.3.3,
- **Tensile strength test**, in accordance with ISO 8536-4:2019, Annex A.4

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 device's referred device (K151650):

- **Cytotoxicity** to ISO 10993-5
- **Sensitization** to ISO 10993-10
- **Intracutaneous reactivity** to ISO 10993-10
- **Acute systemic toxicity** to ISO 10993-11
- **14-day subacute/Subchronic systemic toxicity** to ISO 10993-11
- **In-vitro hemolysis assessment** to ISO 10993-4
- **Material mediated pyrogenicity** to ISO 10993-11
- **Particulate matter limits** 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* was conducted on the Subject device
- **EO residues limits** to ISO 10993-7:2008, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residu*als/Technical Corrigendum 1:2009/Amd.1:2019 for neonates and infants, as defined by the amended standard's patient population categories

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* 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™ *Transfer Injector* (K251722)** is substantially equivalent to the **Predicate, ProSeal™ *Injector Plus* (K240171)**, with respect to the

indications for use, principles of operation and technological characteristics