October 10, 2024

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

Re: K241735
Trade/Device Name: ProSeal™ In Line Pump Set (423850)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: September 12, 2024
Received: September 12, 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)*
K241735

Device Name
ProSeal™ In Line Pump Set (423850)

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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K241735 – 510(k) Summary

I. Submitter

Epic Medical Pte. Ltd.
105 Cecil Street #20-04,
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Singapore 069534
Phone: +65 9635 2618 / +66 81 761 5292

Contact Person: Mr. Freddie LEE, Chief Executive Officer/ Managing Director
Date Prepared: October 10, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K241735
Trade/ Device Name:	ProSeal™ *In Line Pump Set* (423850)
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
Classification 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:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

IV. Device Description

The purpose of this Special 510(k) Submission is to seek FDA clearance prior to the introduction in the US, of an additional device in the ProSeal™ *CSTD* sub-grouping - ProSeal™ *Adaptor/Connector* — the Subject **ProSeal™ *In Line Pump Set***. This device is an addition to the ProSeal™ *CSTD* system of devices (cleared K241823), enhancing the completeness of the portfolio of ProSeal™ *CSTD* system.

The ProSeal™ *CSTD* devices are single-use, sterile, non-pyrogenic *CSTD* component devices that are fitted to each other. They are used as sterile interfaces for the closed injections and withdrawals of liquids into and from the ProSeal™ *CSTD* component devices and external transfer devices.

The **ProSeal™ *In Line Pump Set*** is a closed system in-line IV infusate/drug transfer adapter/ connector for providing closed system protection during hazardous drug administration when connected to a standard IV set at its distal end, with the proximal end attached to a mating ProSeal™ *Injection Site* (K240433) of a ProSeal™ *CSTD* component device such as the eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241442).

The change proposed in this 510(k) Submission to the existing ProSeal™ *CSTD* devices is as follows:

- Addition of I.V. bag spike port

V. Indications for Use Statement (unchanged)

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.

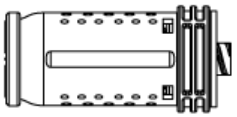
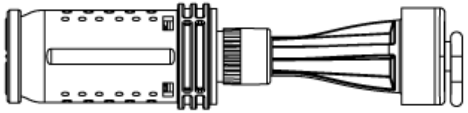
VI. Comparison of Technological Characteristics

The Predicate device (and a component/subassembly of the Subject device) is the **ProSeal™ *Injector Plus*** (cleared K240171). The Subject device and the Predicate device share the following key characteristics:

- Principles of operation
- Closed system technology
- Preventing needlestick injuries
- Spike port subcomponent & material
- Primary package top web
- Sterilization method
- Validated shelf-life
- Single-use only
- Labelling specifications

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

Characteristic compared	**Predicate Device *(K240171)*** **ProSeal™ *Injector Plus***	**Subject Device *(K241735)*** **ProSeal™ *In Line Pump Set***	Comment/ Discussion
Intended Use and *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."	"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
Common name	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System	Same
Primary product code	ONB	ONB	Same
Primary regulation number	21 CFR 880.5440	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
℞/ Prescription use	℞ only	℞ only	Same
Principles of operation	A component device of a multi-component system; devices are intended to be used in combination with other component devices of the ProSeal™ *CSTD*, manually manipulated	A component device of a multi-component system; devices are intended to be used in combination with other component devices of the ProSeal™ *CSTD*, manually manipulated	Same

Characteristic compared	**Predicate Device *(K240171)*** **ProSeal™ *Injector Plus***	**Subject Device *(K241735)*** **ProSeal™ *In Line Pump Set***	Comment/ Discussion
Closed system technology	Mating ProSeal™ devices are sealed with resealing membranes. When devices are joined together, the two membranes are pressed, thus creating a secured fluid path	Mating ProSeal™ devices are sealed with resealing membranes. When devices are joined together, the two membranes are pressed, thus creating a secured fluid path	Same
	Physical barrier to prevent all drug masses from crossing the system boundary	Physical barrier to prevent all drug masses from crossing the system boundary	Same
Preventing needlestick injuries	The ProSeal™ *Injector Plus* (K240171) Predicate device, is encapsulated with a cannula and inaccessible to users	The ProSeal™ *Injector Plus* (K240171), ***a component/subassembly of the* Subject device**, is encapsulated with a cannula and inaccessible to users	Same
Components	ProSeal™ *Injector Plus*	ProSeal™ *Injector Plus* and I.V. bag spike port	Different, See **Comment #1**
Access port/connector to external transfer device	 Access to ProSeal™ *Injector Plus* is **a female Luer lock port** by which an external MLL syringe without needle could be connected	 Access to ProSeal™ *In Line Pump Set* is **a TPE spiking port stopper**, through which a bag spike of an external administration set could be connected	Different, See **Comment #2**
Spike port subcomponent & material	Epic Medical Pte Ltd's cleared eZSURE™ *Empty Fluid Container* (K223674), *2-port sub-assembly for IV Bag* (consisting of an integrated spike port)	Subject device's **spike port is of the same configuration** as the eZSURE™ *Empty Fluid Container* (K223674), *2-port sub-assembly for IV Bag's* integrated spike port	Same
	PP without DEHP*in K240433, MLL connector of ProSeal™ *Injection Site*	**PP** without DEHP*, same as K240433, MLL connector of ProSeal™ *Injection Site*	Same
	eZSURE™ *EFC's spiking port stopper* is made of TPE	Subject device's **spiking port stopper is made of the same TPE**	Same

Characteristic compared	**Predicate Device *(K240171)*** **ProSeal™ *Injector Plus***	**Subject Device *(K241735)*** **ProSeal™ *In Line Pump Set***	Comment/ Discussion
Primary package top web	Medical grade paper and medical plastic film, heat sealed	Medical grade paper and medical plastic film, heat sealed	Same
Sterilization method	Ethylene Oxide, EO, SAL 10^{-}	Ethylene Oxide, EO, SAL 10^{-6}	
Validated shelf life	3 years (36 months)	3 years (36 months)	Same
Reuse or single-use	Single-use only	Single-use only	Same
Labeling specifications	Meets the requirements specified in 21 CFR 801	Meets the requirements specified in 21 CFR 801	Same

* 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.

Discussion of difference in technological characteristic

Comment #1

Submission K241735 is for an FDA clearance of the ProSeal™ *In Line Pump Set*, a single component device to the ProSeal™ *CSTD* system of component devices. Compared to Predicate K240171, the application was for the addition of another single component device to the ProSeal™ *Injector Plus*, to the same ProSeal™ *CSTD* system of component devices. This does not raise different questions of safety and effectiveness as the Subject device is designed to and validated for use with other appropriate component devices of the same ProSeal™ *CSTD* system, for the same intended use. Bench top, biocompatibility, and sterility data demonstrate the difference does not raise different questions in safety and effectiveness. Further details are described in section VII.

Comment #2

Subject device's spiking port and spiking port stopper are made of the same materials and of the same configurations (design and dimensions) as the eZSURE™ *Empty Fluid Container* (K223674), 2-port sub-assembly for IV bag's integrated spiking port, spiking port stopper. Subject device's ProSeal™ *Injector Plus* is the same as the ProSeal™ *Injector Plus* (K240171) with no differences in material, design, and dimensions.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The sterile, single-use, non-pyrogenic ProSeal™ *In Line Pump Set* described in this Summary was determined to be in conformance with the following ISO and FDA recognized standards:

- ANSI AAMI CN27:2021, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*
- ISO 7864: 2016, *Sterile hypodermic needles for single use – Requirements and test methods.*
- 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 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*
- *Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)]---Guidance-for-Industry-and-FDA-Staff*

Bench performance verifications and validations referred to and performed on the Subject device are as follows:

- Leak integrity testing per ISO 8536-4:2019, paragraph 7.2 and Annex A.3 performed on the Subject device
- Liquid leakage testing, per ISO 8536-4:2019, paragraph 7.2, performed on the Subject device using NaCl 0.9%
- Testing of flow rate, infusion set without air-inlet device per ISO 8536-4:2019, paragraph 7.1 and Annex A.5.1, performed on the Subject device
- The following performance testing were performed under K240171, per Luer lock connection tests specified in ISO 80369-7: 2021:
  - 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

To be continued…

- The following sharps injury protection tests were performed under K240171 per ISO 23908:2011,
  - Drop test
  - Flexural force test
  - Tensile force test
  - Compression force test
  - Testing access to the sharp in safe mode
- Device leakage integrity tests were performed under K240171 per ISO 8536-4:2019
- Needle bonding strength test was performed under K240171 per ISO 7864:2016
- Injector Plus cap removal force test was performed under K240171 per ISO 8536-4: 2019
- The following performance testing were performed under K223674, per standards specified hereunder:
  - Resistance to temperature, pressure and leakage, per ISO 15747: 2018, Annex A.3
  - Resistance to dropping, per ISO 15747: 2018, Annex A.4
  - Water vapor impermeability, per ISO 15747: 2018, Annex A.6
  - Spiking port penetration ability, per ISO 15747: 2018, Annex A.8
  - Spiking port adhesion strength, per ISO 15747: 2018, Annex A.9
  - Particulate non-contamination, per ISO 15747: 2018, Annex A.6
  - Impermeability to microorganism, per ISO 15747: 2018, Annex C.2
- Testing to (draft) NIOSH CSTD Test Protocol under K240171
- Microbial ingress/ microbiological integrity testing, per the FDA guidance listed in paragraph 1 in this sub-section, and ANSI AAMI CN27:2021 (functional) from testing data on the existing devices, cleared under K240171 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 are referred to from testing on the devices, under K240171 and K223674:

- 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 Acute Systemic Toxicity to ISO 10993-11
- In-vitro Hemolysis Assessment to ISO 10993-4
- Material Mediated Pyrogenicity to ISO 10993-11
- Chemical Characterization and Toxicological Risk Assessment to ISO 10993-18 and ISO 10993-17
- Particulate matter testing to USP <788> *Particulate Matter in Injections*

C. Sterility, Shipping, and Shelf-Life

The Subject device, like the Predicate device and the I.V. bag spike (a component/subassembly of 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:

- 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*
- 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 Subject device was determined to be substantially equivalent to the Predicate, and there were no new questions of its safety or effectiveness. The Subject **ProSeal™ *In Line Pump Set*** is substantially equivalent to the Predicate, the **ProSeal™ *Injector Plus***, with respect to the indications for use, principles of operation and technological characteristics.