May 21, 2024

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

Re: K240433
Trade/Device Name: ProSeal™ Injection Site Extended Male Luer Lock (model 422140)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: April 19, 2024
Received: April 19, 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.

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)*
K240433

Device Name
ProSeal™ Injection Site External Male Luer Lock (model 422140)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K240433 – 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 20, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Traditional

II. Subject Device

510(k) Number:	K240433
Trade/ Device Name:	ProSeal™ *Injection Site Extended Male Luer Lock* (model 422140)
Common/ Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer Device
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

III. Predicate

510(k) Number:	K240171
Trade/ Device Name:	ProSeal™ *CSTD* (with the *Injector Plus* (model no. 421050))
Common/ Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer Device
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class: II
Product Code:	ONB

IV. Device Description

The purpose of this 510(k) Submission is to seek FDA clearance prior to the introduction in the US, of a new ProSeal™ *Closed System (drug) Transfer Device (CSTD)* component device — the Subject ProSeal™ *Injection Site Extended Male Luer Lock* (ProSeal™ *Injection Site*). This device is an addition to the ProSeal™ *CSTD* system of devices. The existing system component device, in the same sub-grouping, and also the nominated Predicate device, is the ProSeal™ *CSTD's Connector*.

The ProSeal™ *CSTD* (cleared K240171) is a sterile, single-use *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™ *Injection Site* is a component of the ProSeal™ *CSTD* system intended for connection with the interface membranes between any standard female Luer lock port and ProSeal™ *CSTD* component devices, for close system fluid transfer. It is one variant of the cleared ProSeal™ *Connector*, a component device of the ProSeal™ *CSTD* system. When connected to a female Luer lock port and engaged with a ProSeal™ *Injector* or a ProSeal™ *Injector Plus* (K240171) (Syringe Adaptor), fluid can be transferred to the connecting device in a closed system. The ProSeal™ *Injection Site* and its corresponding interface membranes exhibit a dry connection with the communicating surfaces in a fluid transfer. The use of this component and its appropriate ProSeal™ *CSTD* component device reduces the risk of microbial ingress for up to 168 hours of 7 days, when use as intended.

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

- the double membrane septum design utilizes self-sealing elastomeric membranes, tightly fit together, when the system components engage, creating an air-tight and leak proof seal.

The modifications to the existing ProSeal™ *Connector*, proposed in this Submission, are:

- Geometric design change
- Material change of membrane from TPE to polyisoprene

V. *Indications for Use* Statement

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

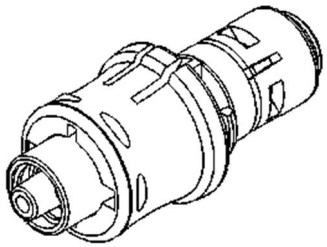
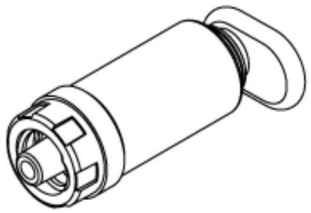
VI. Comparison of Technological Characteristics

The ProSeal™ *Injection Site Extended Male Luer Lock*, a system component of the ProSeal™ *CSTD* and the predicate system component of interest, the ProSeal™ *Connector*, share the following key characteristics:

- same closed system technology
- same interface between system components
- same of Luer lock connection to fit any female Luer lock port
- same sterile barrier packaging
- same sterilization method
- same shelf-life

An overview table summarizing the comparison of key characteristics between the Subject ProSeal™ *Injection Site* and the predicate ProSeal™ *CSTD*'s ProSeal™ *Connector*, is provided hereunder.

Characteristic compared	**Predicate Device** ProSeal™ *CSTD*'s ProSeal™ *Connector* (cleared K240171)	**Subject Device** ProSeal™ *CSTD,* ProSeal™ *Injection Site Extended Male Luer Lock* (K240433)	**Comment/ Discussion**
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
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 or pharmacists/ clinical setting	Adequately trained health care professionals or pharmacists/ clinical setting	Same
Intended drug type	Parenteral drugs	Parenteral drugs	Same
℞/ Prescription use	℞ only	℞ only	Same
Closed system technology	Physical barrier to prevent all mass from crossing the system boundary	Physical barrier to prevent all mass from crossing the system boundary	Same
Interface between system components	Elastomeric resealing double membrane	Elastomeric resealing double membrane	Same

Characteristic compared	**Predicate Device** ProSeal™ *CSTD*'s ProSeal™ *Connector* (cleared K240171)	**Subject Device** ProSeal™ *CSTD,* ProSeal™ *Injection Site Extended Male Luer Lock* (K240433)	**Comment/ Discussion**
Fitting to external Luer Lock syringe	Female Luer Lock conforms to ISO 80369-7:2016	Female Luer Lock conforms to ISO 80369-7:2016	Same
System component devices	1. ProSeal™ *Injector* (model 421010) (K192075) 2. ProSeal™ *Injector Plus* (addition of model 421050 – K240171, cleared on March 28, 2024) 3. ProSeal™ *Connector* (model 422010) (K192075) 4. ProSeal™ *Vial Adaptor* (3 models 4200X0, for vial neck sizes and pressure equalization) (K192075) 5. ProSeal™ *Assembly Fixture* (Fixture for ProSeal™ *Vial Adaptor* assembly, model 424010) (K192075)	1. ProSeal™ *Injector* (model 421010) 2. ProSeal™ *Injector Plus* (model 421050) 3. ProSeal™ *Connector* (422010) 4. **Proposed ProSeal™ *Injection Site Extended Male Luer Lock* (Subject device, K240433)** 5. ProSeal™ *Vial Adaptor* (3 models 4200X0, for vial neck sizes and pressure equalization) 6. ProSeal™ *Assembly Fixture* (Fixture for ProSeal™ *Vial Adaptor* assembly, model 424010)	Different, the Subject system component device **(#4 in the column Subject Device)**, is an addition to the five (5) existing component devices of ProSeal™ *CSTD* (K240171), and is indicated in **bold face texts.** Differences are addressed in the two rows hereunder
Fluid path materials of construction (ProSeal™ *Connector*)	Polypropylene (PP), **thermoplastic elastomer (TPE)**	Polypropylene (PP), **polyisoprene (IR)**	Different, See **Comment #1**
Geometric design – unlock ring and protective cap	 **provided with** unlock ring and **without** removable protective cap	 **without** unlock ring and **provided with** removable protective cap	Different, See **Comment #2**

Characteristic compared	**Predicate Device** ProSeal™ *CSTD*'s ProSeal™ *Connector* (cleared K240171)	**Subject Device** ProSeal™ *CSTD,* ProSeal™ *Injection Site Extended Male Luer Lock* (K240433)	**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^{-6}	Ethylene Oxide, EO, SAL 10^{-6}	Same
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

Discussion of difference in technological characteristics

Comment #1

The membrane material of Subject device is polyisoprene rubber (IR), compared with thermoplastic elastomer (TPE) in the Predicate device (cleared K240171). The same IR membrane subcomponent is present in Epic Medical Pte Ltd - the applicant's - ToxiSeal™ *Vial Adaptor with External Balloon* (cleared K222929) and it had been validated to have conformed with ISO 10993-1: 2018, and to the functional performance requirements in section VII hereunder.

Comment #2

The differences in design - the removal of the unlock ring, and the inclusion of a protective cap, have been evaluated through ISO 80369-7: 2021 testing and ISO 8536-4: 2019 testing respectively. The exclusion of the unlock ring and the inclusion of the protective cap - both changes not in the fluid path - were found to have met the functional performance acceptance criteria therein. Further details are summarized in section VII.A.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The ProSeal™ *Injection Site Extended Male Luer Lock* with modifications described in section IV in this Summary - geometric design change, and material change of membrane from TPE to polyisoprene - were tested and demonstrated to be in conformance with the following ISO and FDA recognized standards/ FDA guidance document:

- AAMI CN27: 2021, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular application*s.
- ISO 8536-4: 2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 80369-7: 2021, *Small-bore connectors for liquids and gases in healthcare application - Part 7, Connectors for intravascular or hypodermic applications*
- *US FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)], Issued on July 11, 2008*

Bench performance verifications and validations conducted:

- 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
- Device leakage integrity test
- Vapor containment test per NIOSH 2016 draft protocol
- Microbial ingress test per FDA guidance and AAMI CN27: 2021

B. Biocompatibility

In accordance with ISO 10993-1: 2018, the ProSeal™ *Injection Site Male Luer Lock*, just like the existing device, is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing are referenced from testing on the existing device and referred-to device:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- 14-day Subacute/ Subchronic Acute Systemic Toxicity
- In-vitro Hemolysis Assessment
- Material Mediated Pyrogenicity
- Chemical characterization and Toxicological Risk Assessment

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

C. Sterility, Shipping, and Shelf-Life

The Subject device, like the existing 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:

- AAMI TIR 28: 2016, *Product Adoption and process equivalence for ethylene oxide sterilization*
- USP <85>, *Bacterial endotoxin test*
- ASTM F1980-16, *Standard guide for accelerated aging of sterile barrier systems for medical devices*
- ASTM F88/ F88M-21, *Sterile barrier packaging Testing* performed on the existing device: *Seal strength*
- ISO 10993-7: 2008/ Amd 1: 2019, *Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals; Amendment 1: Applicability of allowable limits for neonates and infants*

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 ProSeal™ *Injection Site Extended Male Luer Lock* is substantially equivalent to the Predicate, ProSeal™ *CSTD's Connector*, with respect to the indications for use, principles of operation and technological characteristics.