March 28, 2024

Epic Medical Pte. Ltd.
Freddie Lee
CEO
105 Cecil , 20-01 The Octagon
Singapore, Singapore 069534
Singapore

Re: K240171
Trade/Device Name: ProSeal™ Injector Plus (Model no. 421050)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: March 1, 2024
Received: March 1, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240171

Device Name
ProSeal™ Injector Plus (Model no. 421050)

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 contaminants into the drug or fluid path for up to 168 hours or 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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K240171 – 510(k) Summary

I. Submitter

Epic Medical Pte. Ltd.
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Phone: +65 9635 2618 / +66 81 761 5292

Contact Person: Mr. Freddie LEE, Chief Executive Officer/ Managing Director
Date Prepared: March 15, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

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

III. Predicate

510(k) Number:	K192075
Trade/ Device Name:	ProSeal™ *CSTD, Injector*, (model 421010) (submitted by Epic Medical Pte. Ltd.)
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 a modified design of a ProSeal™ *CSTD* component device — the Subject ProSeal™ *Injector Plus* (adapter to the Luer Lock tip syringe). This device is an addition to the ProSeal™ *CSTD* system of devices. The existing system component device, and also the nominated Predicate device, is the ProSeal™ *Injector*.

The ProSeal™ *CSTD* (K192075) 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™ *Injector Plus* is a component of the ProSeal™ *CSTD* system intended for connection to a standard Luer lock syringe. It is one variant of the cleared ProSeal™ *Injector*, a component device of the ProSeal™ *CSTD* system. Just like the ProSeal™ *Injector*, a non-latex elastomeric membrane covers the liquid transfer cannula tip of the ProSeal™ *Injector Plus*. It incorporates a clamp mechanism that reversibly connects to the other component devices of the ProSeal™ *CSTD* system. The ProSeal™ *Injector Plus*, like the ProSeal™ *Injector* includes a stainless steel cannula that is always shielded: during preparation, use and disposal. The ProSeal™ *Injector Plus* is supplied with a protective cap.

The closed transfer of liquid that takes place with the use of the ProSeal™ *CSTD* system (K192075) as follows:

- A double membrane septum utilizing self-sealing elastomeric membranes tightly fits together when the system components engage. A cannula within the ProSeal™ *Injector Plus* housing perforates the double membrane for the transfer of liquid. When the cannula is retracted, the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols, and spills, and also minimizing the risk of microbial contamination.

The proposed modifications are:

- Geometric change of needle hub design
- Geometric change of housing design
- Needle bonding method, from UV glue to over-molding
- Change of housing material from polycarbonate to polyoxymethylene
- Addition of protective cap to *Injector Plus*

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

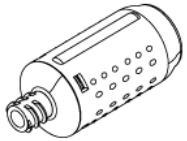
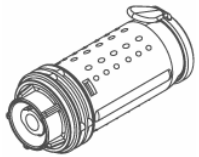
The ProSeal™ *Injector Plus*, a system component of the ProSeal™ *CSTD* and the predicate system component of interest, the ProSeal™ *Injector*, share the following key characteristics:

- same closed system technology
- same interface between system components
- same Luer lock connection to fit to syringe
- same sharps protection features
- same sterile barrier packaging
- same sterilization method
- same shelf-life

An overview table summarizing the comparison between of key characteristics between the Subject ProSeal™ *Injector Plus* and the Predicate ProSeal™ *CSTD - Injector* is provided hereunder.

Characteristic compared	**Predicate Device** ProSeal™ *CSTD* (K192075) ProSeal™ *Injector* (model 421010)	**Subject Device** ProSeal™ *CSTD* (K240171) ProSeal™ *Injector Plus* (model 421050)	**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

Characteristic compared	**Predicate Device** ProSeal™ *CSTD* (K192075) ProSeal™ *Injector* (model 421010)	**Subject Device** ProSeal™ *CSTD* (K240171) ProSeal™ *Injector Plus* (model 421050)	**Comment/ Discussion**
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
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	**ProSeal Injector (model 421010)** ProSeal Connector (422010) ProSeal Vial Adaptor (models 420020, 420030, 420040 for different neck sizes and pressure equalization) ProSeal Assembly Fixture (Fixture for ProSeal Vial Adaptor assembly, model 424010)	**ProSeal Injector Plus (model 421050)** ProSeal Connector (422010) ProSeal Vial Adaptor (models 420020, 420030, 420040 for different neck sizes and pressure equalization) ProSeal Assembly Fixture (Fixture for ProSeal Vial Adaptor assembly, model 424010)	Different difference discussed in **Comments #1 and #2**
Materials of construction in the fluid path of Injector	Polypropylene (PP), stainless steel (SUS 304), & thermoplastic elastomer (TPE)	Polypropylene (PP), stainless steel (SUS 304), & thermoplastic elastomer (TPE))	Same

Characteristic compared	**Predicate Device** ProSeal™ *CSTD* (K192075) ProSeal™ *Injector* (model 421010)	**Subject Device** ProSeal™ *CSTD* (K240171) ProSeal™ *Injector Plus* (model 421050)	**Comment/ Discussion**
Cannula-to-hub assembly	UV adhesive for medical assembly	Hub over-molding onto cannula without adhesive	Different, See C**omment #1**
Sharp protection feature	The sharps are inaccessible to users by design and had been verified according to ISO 23908: 2011	The sharps are inaccessible to users by design and had been verified according to ISO 23908: 2011	Same
Extended FLL shield collar feature and protective cap	 without extended FLL shield collar nor protective cap	 incorporated with extended FLL shield collar and provided with removable protective cap	Different, See **Comment #2**
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 differences in technological characteristics

Comment #1

The difference in how the cannula is attached to the hub during the production process has been evaluated through needle pull strength testing specified in ISO 7864: 2016, the same test method and acceptance criteria as ProSeal™ *CSTD* (K192075), and found to have also met the functional performance acceptance criteria. Details are summarized in section VII.A.

Comment #2

The differences in design - the addition of a shield collar, and a protective cap - have been evaluated through ISO 80369-7: 2021 testing and ISO 8536-4: 2019 testing respectively. The Luer lock connection and the protective cap 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™ *Injector Plus* described in this Summary, with modifications listed in section IV, were tested and demonstrated to be in conformance with the following ISO and FDA recognized standards:

- 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 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 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
- 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
- Cap removal force test

B. Biocompatibility

In accordance with ISO 10993-1: 2018, the ProSeal™ *Injector Plus*, 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 devices:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- 14-day Subacute/ Subchronic Acute Systemic Toxicity
- In-vitro Hemolysis Assessment
- Material Mediated Pyrogenicity
- Chemical Characterization as per ISO 10993 Part-18: 2020(E)/AMD-1: 2022 and ISO 10993-12: 2021 (E).

Particulate matter testing was conducted 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. Conclusion

The differences between the Predicate and the Subject device do not raise any new or different questions of safety or effectiveness. The ProSeal™ *CSTD - Injector Plus* is substantially equivalent to the Predicate, the ProSeal™ *CSTD - Injector*, with respect to the indications for use, principles of operation and technological characteristics.