August 30, 2024

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

Re: K241823
Trade/Device Name: ToxiSeal™ Vial Adaptor
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: June 24, 2024
Received: July 31, 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,

Porsche Bennett

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)*
K241823

Device Name
ToxiSeal™ Vial Adaptor

Indications for Use *(Describe)*
The ToxiSeal™ Vial Adaptor 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 device also prevents the introduction of microbial contaminations 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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K241823 – 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: August 30, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: **Special**

II. Subject Device

510(k) Number:	K241823
Trade/ Device Name:	**ToxiSeal™** ***Vial Adaptor***
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
Classification Product Code:	ONB

III. Predicate

510(k) Number:	K241476
Trade/ Device Name:	**ToxiSeal™** ***Vial Adaptor with External Flip Balloon***
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
Classification 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 ToxiSeal™ *Vial Adaptor* — **the Subject ToxiSeal™ *Vial Adaptor***. This device is an addition to the ProSeal™ *CSTD* system of devices (cleared K240433). The nominated Predicate device is **the existing ToxiSeal™ *Vial Adaptor with External Flip Balloon* (cleared K241476)**.

The ToxiSeal™ *Vial Adaptor* devices are single-use, sterile, non-pyrogenic CSTD drug vial adaptors that are fitted to the drug vials and are sealed against the closures of the vials. They are used as sterile interfaces between the drug vials and the ProSeal™ *Injector* or the ProSeal™ *Injector Plus* (both are syringe adaptors) for the injection of diluents into the drug vials and/or withdrawal of liquids from the vials.

The ToxiSeal™ *Vial Adaptor* devices, designed to be used with the cleared ProSeal™ *Injector* or *Injector Plus* within the ProSeal™ *CSTD* system (K240433), are variants of *CSTD* vial *adaptor* component device offerings to the ProSeal™ *CSTD* system. The additions enhance the completeness of the portfolio of ProSeal™ *CSTD* devices system.

Changes proposed in this Special 510(k) Submission are as follow:

- Removed external balloon and added activated carbon filter

V. Indications for Use Statement

The ToxiSeal™ *Vial Adaptor* 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 device also prevents the introduction of microbial contaminations into the drug or fluid path for up to 168 hours (or 7 days) when used as intended.

VI. Comparison of Technological Characteristics

The Subject device and the Predicate device share the following key characteristics:

- System components of the ProSeal™ *CSTD*
- Closed System Technology
- Interface between system components
- Membrane material
- Hydrophobic filter
- Intended *Injectors*
- Sterile barrier packaging
- Sterilization process
- Shelf-life
- Single-use

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

Side-by-side comparison of technology & design characteristics

Characteristics compared	Predicate Device (*K241476*) **ToxiSeal™ *Vial Adaptor with External Flip Balloon***	Subject Device (*K241823*) **ToxiSeal™ *Vial Adaptor***	Detailed discussion and comparative evaluation
Intended use and *Indications for Use* statement	"The **ToxiSeal™ *Vial Adaptor with External Flip Balloon*** 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 device also prevents the introduction of microbial contaminations into the drug or fluid path for up to 168 hours (or 7 days) when used as intended."	"The **ToxiSeal™ *Vial Adaptor*** 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 device also prevents the introduction of microbial contaminations into the drug or fluid path for up to 168 hours (or 7 days) when used as intended."	Same
Intended user population	Adequately trained health care professionals or pharmacists	Adequately trained health care professionals or pharmacists	Same
Intended use environment	Clinical setting	Clinical setting	Same
Intended drug type	Parenteral drugs	Parenteral drugs	Same
Single use or reusable	Single use only	Single use only	Same
Prescription use or over-the-counter use	℞ only	℞ only	Same
Labeling specifications	Meets the requirements specified in 21 CFR 801	Meets the requirements specified in 21 CFR 801	Same

Side-by-side comparison of technology & design characteristics

Characteristics compared	Predicate Device (*K241476*) **ToxiSeal™ *Vial Adaptor with External Flip Balloon***	Subject Device (*K241823*) **ToxiSeal™ *Vial Adaptor***	Detailed discussion and comparative evaluation
System component devices	1. ProSeal™ *Injector* (model 421010) (K241476) 2. ProSeal™ *Injector Plus* (model 421050) (K241476) 3. ProSeal™ *Connector* (422010) (K241476) 4. ProSeal™ *Injection Site Extended Male Luer Lock* (K241476) 5. ProSeal™ *Vial Adaptor* (3 models 4200X0, for options of vial neck sizes and pressure equalizations) K241476) 6. ToxiSeal™ *Vial Adaptor with External Balloon* (K241476) 7. ToxiSeal™ *Vial Adaptor with External Flip Balloon* (K241476) 8. eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241476) 9. ProSeal™ *Closed System Administration Set* (K230343) 10. ProSeal™ *Assembly Fixture* (Fixture for ProSeal™ *Vial Adaptor* assembly, model 424010) (K241476)	1. ProSeal™ *Injector* (model 421010) (K241476) 2. ProSeal™ *Injector Plus* (model 421050) (K241476) 3. ProSeal™ *Connector* (422010) (K241476) 4. ProSeal™ *Injection Site Extended Male Luer Lock* (K241476) 5. ProSeal™ *Vial Adaptor* (3 models 4200X0, for options of vial neck sizes and pressure equalizations) (K241476) 6. ToxiSeal™ *Vial Adaptor with External Balloon* (K241476) 7. ToxiSeal™ *Vial Adaptor with External Flip Balloon* (K241476) 8. **ToxiSeal™ *Vial Adaptor* (the Subject device)** 9. eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241476) 10. ProSeal™ *Closed System Administration Set* (K230343) 11. ProSeal™ *Assembly Fixture* (Fixture for ProSeal™ *Vial Adaptor* assembly, model 424010) (K241476)	Different, the Subject system component device **(#8 in the column <u>Subject Device</u>)**, is an addition to the existing ten (10) cleared component devices of ProSeal™ *CSTD* (K241476) and the ProSeal™ *Closed System Administration Set* (K230343), indicated in **bold face texts.** Differences are addressed in **Comments #1** and **#2** under this table.
Closed System Technology	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
Interface between system components	Elastomeric resealing double-membrane	Elastomeric resealing double-membrane	Same
Intended *Injector* for use with the Subject device	ProSeal™ *Injector* (model 421010) or **ProSeal™ *Injector Plus* (model 421050) (cleared K241071 & K240433)**, both Male Luer Lock tip	ProSeal™ *Injector* (model 421010) or **ProSeal™ *Injector Plus* (model 421050) (cleared K241071 & K240433)**, both Male Luer Lock tip	Same

Side-by-side comparison of technology & design characteristics

Characteristics compared	Predicate Device (*K241476*) **ToxiSeal™ *Vial Adaptor with External Flip Balloon***	Subject Device (*K241823*) **ToxiSeal™ *Vial Adaptor***	Detailed discussion and comparative evaluation
Membrane material	Isoprene rubber (IR)	Isoprene rubber (IR)	Same
Hydrophobic filter (non-fluid path)	Polytetrafluoroethylene (PTFE)	Polytetrafluoroethylene (PTFE)	Same
Activated carbon filter	None (carbon filter was removed in ToxiSeal™ Vial Adaptor with External Flip Balloon (K241476))	Activated carbon	Different, See **Comment #1**
External balloon (non-fluid path)	Polyethylene terephthalate -Polyethylene (PET/PE) laminate and Polyethylene (PE)	None	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

Discussion of differences in technological characteristics

Comment #1

An activated carbon filter, which was not present in the Predicate (K241476) is now included for the Subject device. The filter adsorbs drug vapors within the vial adaptor, ensuring safety for healthcare workers and minimizing contamination risk. This difference is considered and addressed in the verification testing of the Subject device over the shelf life, to the following standards: ISO 8536-4:2019, subclause A.3.3 and NIOSH 2016, *Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs,* and found it did not raise any new or different questions of safety or effectiveness. Details are provided in section VII.

Comment #2

The Subject device does not include an external balloon – a pressure equalization mechanism. This difference of not having an external balloon together with the inclusion of an activated carbon filter, was considered and addressed in the verification tests described in **Comment #1**. Bench performance verification testing of the Subject device over the shelf life was conducted to the following standards: ISO 8536-4:2019, subclause A.3.3 and NIOSH 2016, *Performance Test Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*. Testing found it did not raise any new or different questions of safety or effectiveness. Further details are provided in section VII hereunder.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The sterile, single-use, non-pyrogenic ToxiSeal™ *Vial Adaptor* devices described in this Summary were evaluated to be in conformance with the following ISO and FDA recognized standards:

- ISO 8536-2:2010, *Infusion equipment for medical use – Part 2: Closures for infusion bottles*
- ISO 8536-4:2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 8871-5:2016, *Elastomeric parts for parenterals and for devices for pharmaceutical use Part 5: Functional requirements and testing*
- ISO 22413:2021, *Transfer sets for pharmaceutical preparations – Requirements and* test *methods*

Bench performance verifications and validations referred to and performed on the Subject device as detailed hereunder:

- Leak integrity testing (air- and liquid-tightness) per ISO 8536-4:2019, paragraph 7.2 and Annex A.3 performed on the Subject devices, and on devices under K241476
- Fragmentation study to ISO 22413 & ISO 8871-5, performed on device under K241476
- Vial Adaptor penetration force testing to ISO 22413, on device under K241476
- Tests for leakages to ISO 8536-4:2019, Annex A.3.3, performed on the Subject device
- Testing to (draft) NIOSH CSTD Test Protocol, performed on the Subject device, and on device under K222929
- Microbial ingress/ microbiological integrity testing conducted on device under K222929

B. Biocompatibility

In accordance with ISO 10993-1: 2018, the Subject devices, are classified as: *Externally Communicating Device*, *Blood Path Indirect*, *Prolonged Contact* (>24hr to 30d). The following testing are referred to, from testing on existing devices of the ProSeal™ *CSTD* system:

- Cytotoxicity to ISO 10993-5 under K192075
- Sensitization to ISO 10993-10 under K192075
- Intracutaneous Reactivity to ISO 10993-10 under K192075
- Acute Systemic Toxicity to ISO 10993-11 under K192075
- 14-day Subacute/ Subchronic Acute Systemic Toxicity to ISO 10993-11 under K192075 and under K222929
- In-vitro Hemolysis Assessment to ISO 10993-4 under K192075 and K192075/S001
- Material Mediated Pyrogenicity to ISO 10993-11 under K192075
- Chemical Characterization and Toxicological Risk Management to ISO 10993-18 and ISO 10993-17 under K192075/S001

Particulate matter testing was conducted in accordance with USP <788> *Particulate Matter in Injections*, and found to have met the acceptance criteria therein, on devices under K192075 and K222929.

C. Sterility, Shipping, and Shelf-Life

The Subject devices, comply 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 conducted under K222929:

- 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* 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.*

VIII. Clinical Tests

Not applicable.

IX. Conclusion

The differences between the Predicate and the Subject device do not raise any new or different questions of safety or effectiveness. The **Subject ToxiSeal™ *Vial Adaptor*** is substantially equivalent to the **Predicate**, the **ToxiSeal™ *Vial Adaptor with External Flip Balloon***, with respect to the indications for use, principles of operation and technological characteristics.