January 22, 2025

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

Re: K243976
Trade/Device Name: ZeroClear™ Bag Access (423100)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: December 20, 2024
Received: December 23, 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,

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)*
K243976

Device Name
ZeroClear™ Bag Access (423100)

Indications for Use *(Describe)*
The ZeroClear™ Bag Access 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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K243976– 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 20, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K243976
Trade/ Device Name:	ZeroClear™ *Bag Access*
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:	K241988
Trade/ Device Name:	ProSeal™ *Closed System Bag Access*
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 ZeroClear™ Bag Access is a part of the ProSeal™ *Closed System drug Transfer Device (CSTD)*, used for injecting and infusing IV fluids and drug solutions from a standard IV bag to a patient. It features a bi-directional Luer lock connector, compatible with ISO 80369-7:2021 male Luer connectors and an ISO 8536-4:2019 compliant IV bag spike, including the applicant's eZSURE™ *Empty Fluid Container* (cleared K223674) and eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (cleared K241442).

This sterile, single-use device used with the appropriate connecting devices, ensures dry connections, minimizes exposure to contaminants and drug vapors, and reduces microbial ingress for up to 7 days. It is intended for use by health care professionals in clinical settings for handling hazardous drugs.

The Subject device will be a part of a grouping of currently, twelve (12) cleared component device offerings, to the ProSeal™ *CSTD* system together with Epic Medical's most recently FDA cleared *CSTD* devices (K241988).

V. *Indications for Use* Statement

The ZeroClear™ *Bag Access* 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 (similar)
2) Primary product code and regulation number
3) Intended user population/ intended use environment
4) Intended drug type
5) Single use or reusable, single patient use

Technological characteristics comparison

Equivalencies – Technology & Design

The *ZeroClear™ Bag Access* 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 different question:

1) Principles of operation
2) Number of access points
3) Sterile barrier packaging
4) Sterilization process
5) Shelf-life

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

Characteristic compared	**Predicate Device** (K241988) ProSeal™ *Closed System Bag Access*	**Subject Device** (K243976) ZeroClear™ *Bag Access*	**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 ZeroClear™ *Bag Access* 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."	Similar, Subject component device's brand name ZeroClear™ is included in the *IFU* statement
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 including pharmacists/ clinical setting	Adequately trained health care professionals including pharmacists/ clinical setting	Same
Intended drug type	Parenteral drugs	Parenteral drugs	Same
Single use or reusable	Single use only, single patient use	Single use only, single patient use	Same
Principles of operation	The infusion bag is connected with the bag access and, in order to create a fluid path connection between the infusion bag and the bag access, they are connected with a matching component device incorporated with a compatible connector. All system components when connected, are sealed airtight and leakage-proof during the fluid transfer process. Transfer is performed through the connection of a matching component device incorporated with a compatible connector, for dispensing into the human veins.	The infusion bag is connected with the bag access and, in order to create a fluid path connection between the infusion bag and the bag access, they are connected with a matching component device incorporated with a compatible connector. All system components when connected, are sealed airtight and leakage-proof during the fluid transfer process. Transfer is performed through the connection of a matching component device incorporated with a compatible connector, for dispensing into the human veins.	Same

Characteristic compared	**Predicate Device** (K241988) ProSeal™ *Closed System Bag Access*	**Subject Device** (K243976) ZeroClear™ *Bag Access*	Comment/ Discussion
Number of access points	Device has 2 access points: 1. Spiking/ administration port, IV spike bag access 2. Injection port/administration port, medication access	Device has 2 access points: 1. Spiking/ administration port, IV spike bag access 2. Injection port/administration port, medication access	Same
Composition of fluid path materials	**Spike material: Polypropylene (PP)** **Medication port material: polyisoprene (IR) and polypropylene (PP)**	**Spike material: Acrylonitrile Butadiene Styrene ((ABS)** **Medication port material: acrylonitrile butadiene styrene, polycarbonate, and silicone**	Different, See **Comment** #1
Intended connector type to be used with the bag spike adapter	**Its ProSeal™ Injection Site port is intended to be connected to Epic Medical Pte Ltd manufacturer's cleared ProSeal™ *Injector* or *Injector Plus* (K240433) male Luer lock tip, connected to an external standard MLL syringe**	**The needle-free Luer activated valve port is directly connected to a component device incorporated with a standard male Luer connector e.g. syringe without needle that complies with ISO 80389-7:2021**	Different, See **Comment #1**
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

Discussion of difference in technological characteristics

Comment #1

Though the Subject device's bag spike and medication port connector type and materials differ from the Predicate, the spike is of the same material as the distal connector subcomponent of the SMARTeZ™ *Pump* (K151650) and the needle-free Luer activated valve (LAV) is the subassembly (with the same subcomponents of the same materials) as the incorporated LAV in the cleared eZSURE™ *Empty Fluid Container* (K223674). The materials of the spike and the LAV subassembly's subcomponents are the same with their corresponding cleared devices in formulation, processing, sterilization, and geometry. Processing is performed at the same molding and assembly processes at our US FDA registered establishment - Epic international (Thailand) Co. Ltd. - and no other chemicals are being added (i.e., plasticizers, fillers, additives, cleaning agents, mold release agents).

Functional tests, viz. the microbial ingress test per the FDA guidance, the ANSI AAMI CN27:2021 and the ISO 80369-7:2021 had been conducted on the cleared device (K223674/S001); and the leak integrity test per ISO 8536-4:2019 had also been performed on the Subject device. Vapor containment test to NIOSH 2016, *Performance Test (draft) Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs* had also been conducted for the Subject device's NFV (LAV) connector. As the difference was considered and addressed in the verification testing of the Subject device over its shelf life, to the aforementioned standards, including FDA recognized standards, and found it did not raise any new or different questions, its safety and effectiveness are assured.

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 and FDA recognized standards, and FDA guidance document:

- ANSI AAMI CN27:2021, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*
- ISO 8536-4: 019, *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 80369-7: 2016, *Small-bore connectors for liquids and gases in healthcare application - Part 7, Connectors for intravascular or hypodermic application*
- NIOSH 2016, *Performance Test (draft) Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs*
- *Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)]---Guidance-for-Industry-and-FDA-Staff*

Bench performance verifications and validations referred-to and performed:

- Airtightness & water leak integrity tests (functional) – per ISO 8536-4:2019, paragraph 7.2 and Annex 3, performed on Subject device
- Tensile strength test (functional) – per ISO 8536-4:2019, paragraph 7.3 and Annex A.4, performed on Subject device
- Spike penetration force test (functional) – per ISO 22413:2021, Section 6.6, Annex A.7, performed on Subject device
- Spike protective cap tests (functional) – per ISO 8536-4:2019, Section 7.13, performed on Subject device
- Vapor containment test per NIOSH CSTD 2016 draft test protocol (functional) from testing data on the Subject device's NFV (LAV) connector
- Microbial ingress test per FDA guidance, ANSI AAMI CN27:2021 and ISO 80369-7:2021 (functional) from testing data on device cleared under K223674/S001

B. Biocompatibility

In accordance with ISO 10993-1:2018, the Subject device just like the existing ProSeal™ *CSTD* devices, is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were performed on devices cleared under K151650, K223674/S001:

- 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 under K223674
- In-vitro Hemolysis Assessment to ISO 10993-4
- Material Mediated Pyrogenicity to ISO 10993-11
- Chemical Requirements to ISO 15747, Annex B on device under K223674
- Chemical Characterization and Toxicological Risk Assessment under K151650

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* and USP <788> *Particulate Matter in Injections*.

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 conducted on devices cleared under K222929:

- Simulated shipping testing per ASTM D 4169-16*, Standard Practice for Performance Testing of Shipping Containers and Systems*
- 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 difference between the Predicate and the Subject device does not raise any new or different questions of safety or effectiveness. The Subject device – **ZeroClear™ *Bag Access*** – is substantially equivalent to the Predicate device, **ProSeal™ *Closed System Bag Access*** (K241988) – with respect to its indications for use, principles of operation and technological characteristics.