August 29, 2025

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

Re: K251814
Trade/Device Name: EZ™ IV Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: July 1, 2025
Received: July 1, 2025

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 -S

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)*
K251814

Device Name
EZ™ IV Administration Set

Indications for Use *(Describe)*
The Administration Sets are intravenous administration sets intended for delivery of medications and fluids from a container into a patient's vascular system.

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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K251814 – 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: August 25, 2025
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Traditional 510(k)

II. Subject Device

510(k) Number:	K251814
Trade/ Device Name:	EZ™ *IV Administration Set*
Common/ Usual Name:	I.V. Administration Set
Regulation Number:	Set, Administration, Intravascular
Regulation Name:	21 CFR 880.5440
Regulatory Class:	Class: II
Product Code:	FPA

III. Predicate

510(k) Number:	K230343
Trade/ Device Name:	ProSeal™ *Closed System Administration Set*
Common/ Usual Name:	I.V. Administration Set
Regulation Number:	Set, Administration, Intravascular
Regulation Name:	21 CFR 880.5440
Regulatory Class:	Class: II
Product Code:	FPA

IV. Purpose of Submission and Device Description

The **EZ™ *IV Administration Set***, the Subject device in this Submission, is a modified series of IV Administration Set, adding to the existing IV Administration Set (cleared K230343). This addition further enhances the completeness of the portfolio of Epic Medical Pte. Ltd.'s IV Administration Sets.

The **EZ™ *IV Administration Set*** is a gravity, single use, disposable, intravenous administration set designed to deliver fluids from a container into a patient's vascular system. The device includes a vented bag spike (air vent 0.1µm) integrated to a drip chamber (not made with DEHP*) featuring a 5-µm particulate filter, a roller clamp, flexible IV tubing (not made with DEHP*), and one (1), two (2) or three (3) needle-free valve (NFV) Y-site connectors. It also features a Luer connector and a priming cap with a 3-µm filter.

The **EZ™ *IV Administration Set*** may be used in combination with standard IV therapy devices commonly used throughout the healthcare settings, such as bag spike, Luer lock adaptor, syringe (MLL) (without needle), and IV extension sets. It is configured to achieve the intended use when used with these standard complementary products.

**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.*

V. *Indications for Use* Statement

The *Administration Sets* are intravenous administration sets intended for delivery of medications and fluids from a container into a patient's vascular system.

VI. Comparison of *Intended Use & Technological Characteristics*

The Subject device, **EZ™ *IV Administration Set***, and the Predicate device, **ProSeal™ *Closed System Administration Set***, share the same intended use and exhibit comparable technological characteristics. A summary of these similarities is provided below:

A. *Intended Use* Comparison

There are no differences between the Subject and Predicate devices that would alter their overall intended use. Both devices are intravenous administration sets intended for the delivery of medications and fluids from a container into a patient's vascular system. The following aspects are equivalent:

1) ***Indications for Use*** statements
2) **Primary product code and regulation number**
3) **Intended user population/intended use environment**
4) **Intended drug type**
5) **Prescription status** (℞ only)
6) **Mode of IV fluid therapy delivery** (gravity-based)

B. *Technological Characteristics* Comparison Equivalencies – *Technology & Design*

The **EZ™ *IV Administration Set*** and the Predicate device share the following design characteristics:

1) **Performance testing** (including functional evaluation**)**
2) **Tubing transparency**
3) **Drops factor** (drops/mL)
4) **Connector type** at distal end (Luer lock)
5) **Particulate contamination level**
6) **Sterile barrier packaging**
7) **Sterilization process**
8) **Shelf-life validation**
9) **Single-use designation**
10) **Labeling specifications** (in accordance with 21 CFR 801)

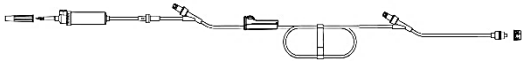
C. Summary

i. No substantial differences were identified that would raise new questions of safety or effectiveness. The Subject device maintains the same intended use and fundamental technological characteristics as the Predicate device. A detailed comparison table is provided below, with additional context and comments included in the **Submitter's Comments** section.

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K230343) **ProSeal™ *Closed System Administration Set***	**Subject Device** (K251814) **EZ™ *IV Administration Set***	Comment
Intended use and *Indications for Use* statement	The *Administration Sets* are intravenous administration sets intended for delivery of medications and fluids from a container into a patient's vascular system.		Same
Primary product code and regulation number	FPA 21 CFR 880.5440		Same
Intended user population/ intended use environment	Adequately trained health care professionals/ clinical setting		Same
Intended drug type	Parenteral drugs		Same
Prescription use or over-the-counter use	℞ only		Same
Mode of IV fluid therapy delivery	Gravity administration		Same
Performance testing (including functional evaluation)	Met requirements of ISO 8536-4:2019, ISO 22413:2021, ISO 10993-1:2018, ANSI/AAMI CN27:2021, ISO 22413:2021, and *Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)]---Guidance- for-Industry-and-FDA-Staff*		Same

Comparison of intended use characteristics and the technological characteristics

Characteristic compared		**Predicate Device** (K230343) **ProSeal™ *Closed System Administration Set***	**Subject Device** (K251814) **EZ™ *IV Administration Set***	Comment
Device construction	**Device final assembly**			Different, see **Comment #1**
	Bag spike or injector	**Closed system injector**	**Integrated bag spike**	
	Drip chamber and IV administration tubings	Present	Present	
	Check valve	**Not present**	**Present**	
	Needleless Y-site	**Not present**	**Present**	
	MLL connector and priming cap	Present	Present	
Composition of fluid-path / -contacting materials		• **Bag spike – Not present** • **Injector – PP, SUS 304 Steel, TPE** • IV tubing – PVC *(not made with DEHP)* • **Check valve – Not present** • MLL connector – ABS • Drip chamber – PVC (*not made with DEHP)*, ABS, polyethylene terephthalate (PET) • **Needleless Y-site – Not present** • Priming cap – PP, Polytetrafluoroethylene (PTFE)	• **Bag spike – Acrylonitrile butadiene styrene (ABS)** • **Injector – Not present** • IV tubing – PVC *(not made with DEHP)* • **Check valve – ABS, silicone** • MLL connector – ABS • Drip chamber – PVC (*not made with DEHP)*, ABS, polyethylene terephthalate (PET) • **Needleless Y-site – PP, ABS, silicone** • Priming cap – PP, Polytetrafluoroethylene (PTFE)	Different, see **Comment #2**

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K230343) **ProSeal™ *Closed System Administration Set***	**Subject Device** (K251814) **EZ™ *IV Administration Set***		Comment
Tubing transparency	The IV tubings are transparent and sufficiently clear so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision			Same
Dimensions of IV set	• Overall set length: - **210 cm (model 423500)** • PVC tubing: - Inner diameter (ID): 3.0 mm - Outer diameter (OD): 4.0 mm	• Overall set length: - **200 cm (model 429170)** - **240 cm (model 429150)** - **280 cm (model 429160)** • PVC tubing: - Inner diameter (ID): 3.0 mm - Outer diameter (OD): 4.0 mm		Different, see **Comment #1**
Drops/mL	20 gtt/mL			Same
Priming volume (including Y-site needlefree connectors' residual volumes in the Subject device)	**11.9 mL** (without Y-site connector)	**For model 429170, 1-Y-site, 200 cm (79'') tubing length**	**14.6 mL**	Different, see **Comment #1**
		For model 429150, 2-Y-site, 240 cm (96'') tubing length	**17.4 mL**	
		For model 429160, 3-Y-site, 280 cm (109'') tubing length	**20.4 mL**	
Connector type at distal side of IV admin set.	External Fitting Male Luer Lock (ISO 80369-7:2021)			Same
Particulate contamination level	Met contamination index, N≤90 according to ISO 8536-4, *Infusion Equipment for Medical Use, Part 4: Infusion sets for single use, gravity feed, Annex A, A.2 - Test for particulate contamination* and USP <788> *Particulate Matter in Injection*s			Same
Sterile barrier packaging	Medical grade paper and medical plastic film, heat sealed			Same
Sterilization process	Ethylene Oxide (EO), SAL 10^{-6}			Same
Shelf-life validation	3 years (36 months)			Same
Reuse or single-use	Single use only			Same
Labeling specifications	Met the requirements specified in 21 CFR 801			Same

ii. Submitter's Comments

Comment #1

The Subject devices differ from the Predicate device in terms of device construction, overall set lengths and priming volumes. These differences did not raise new questions of safety or effectiveness, as both analytical and functional testing were conducted. The results of these tests, summarized in **Section VII.A**, demonstrated that the performance of the Subject devices met the intended use. Therefore, the differences were considered not significant

Comment #2

The Subject devices differ from the Predicate device in material composition. This variation did not raise new questions of safety or effectiveness, as analytical and functional testing were also completed. Biocompatibility testing, chemical characterization and risk analysis – based on data from previously cleared devices – were evaluated for the Subject devices and are summarized in **Section VII.B**. The results confirmed that the devices met biological safety specifications, and the differences were considered not significant

VII. Performance Data Supporting Substantial Equivalence

All performance testing demonstrated and confirmed the safety and effectiveness of the Subject device

A. Performance Testing *(including functional evaluations)*

The Subject device was evaluated for conformance with the following ISO standards and guidance documents:

- **ANSI/AAMI CN27:2021,** *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*
  - **ISO 80369-7:2021,** *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*
  - **ISO 80369-20:2015,** *Small-bore connectors for liquids and gases in healthcare applications (Part 20: Common test methods)*
- **ISO 8536-4:2019,** *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- **ISO 22413:2021,** *Transfer sets for pharmaceutical preparations — Requirements and test methods*
- ***Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)] –*** *Guidance-for-Industry-and-FDA-Staff*

Comprehensive performance verification and validation testing was performed on the Subject device. Additionally, relevant testing data from the Predicate device (K230343/S001) were leveraged to support and demonstrate substantial equivalence. Testing conducted:

On Subject device

- **Air-inlet device tests** per ISO 8536-4:2019
- **Flow rate test** per ISO 8536-4:2019
- **Piercing device penetration force test** per ISO 22413:2021
- **Protective cap removal test** per ISO 8536-4:2019
- **Drip chamber and drip tube tests** per ISO 8536-4:2019
- **Leak integrity tests** per ISO 8536-4:2019 (air leakage under positive pressure, air leakage under negative pressure and fluid leakage)
- **Tensile strength test** per ISO 8536-4:2019

On Predicate device – K230343/S001

- **Particulate contamination tests** per ISO 8536-4:2019
- **Leak integrity tests** per ISO 8536-4:2019
- **Tensile strength test** per ISO 8536-4:2019
- **Tubing tests** per ISO 8536-4:2019
- **Fluid filter test** per ISO 8536-4:2019
- **Drip chamber and drip tube tests** per ISO 8536-4:2019
- **Flow rate test** per ISO 8536-4:2019
- **Luer Lock connection test** per ISO 80369-7:2021

On K230343 (during initial review, tested with *Y-connector*)

- **Testing to relevant subclauses in Clauses 4 and 5 of ANSI/AAMI CN27:2021** on the LAV connector

B. Biocompatibility Testing

In accordance with ISO 10993-1:2018, the Subject device is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24 hr to 30 d). The following tests were conducted on both the Predicate (under K230343/S001) and the Subject device:

- **Cytotoxicity** per ISO 10993-5:2009
- **Sensitization** per ISO 10993-10:2021
- **Intracutaneous reactivity** per ISO 10993-23:2021
- **Acute systemic toxicity** per ISO 10993-11:2017
- **Subacute/subchronic systemic toxicity** per ISO 10993-11:2017
- **In-vitro hemolysis** per ISO 10993-4:2017 & ASTM F756-17
- **Material mediated pyrogenicity** per ISO 10993-11:2017 & USP <151>
- **Chemical characterization and toxicological risk assessment** per ISO 10993-18:2020/AMD-1: 2022 & ISO 10993-17:2002
- **Particulate matter testing** per 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*, on the Predicate and Subject devices
- **EO residues limits** per ISO 10993-7:2008, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residu*als/Technical Corrigendum 1:2009/Amd.1:2019 for neonates and infants, as defined by the amended standard's patient population categories on the Subject device

C. Sterility, Shipping, and Shelf-Life Validation

The Subject device complies with sterilization requirements outlined in 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.* The following testing and evaluations were performed on the existing device (K151650), the Predicate device (K230343) and the Subject device:

- **Simulated shipping testing** per ASTM D 4169-16, *Standard Practice for Performance Testing of Shipping Containers and Systems* under K151650/S004
- **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* under K151650
- **Pyrogen tests** per ANSI/AAMI ST72/2019, *Bacterial endotoxins – Test methods, routing monitoring,* and *alternatives to batch testing,* USP 42-NF 37 <151>, *Pyrogen test (USP rabbit test),* USP 42-NF 37 <161>, *Medical Devices-Bacterial Endotoxin and Pyrogen Tests,* USP 42-NF 37 <85>, *Bacterial Endotoxins Test* under K151650 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* on the Subject device

VIII. Clinical Tests

Not applicable

IX. Conclusion

Based on the comparative analysis and performance data, the **EZ™ *IV Administration Set*** does not raise new questions of safety or effectiveness. Therefore it is substantially equivalent to the Predicate device, **ProSeal™ *CS Administration Set*** (K230343), per US FDA 510(k) requirements