August 1, 2025

Epic Medical Pte. Ltd.
Freddie Lee
CEO/MD, Chief Executive Officer/Managing Director
105 Cecil Street #20-04, The Octagon
Singapore, 069534
Singapore

Re: K252094
Trade/Device Name: eZSURE™ Empty Fluid Container
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. container
Regulatory Class: Class II
Product Code: KPE, ONB
Dated: July 3, 2025
Received: July 3, 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)*
K252094

Device Name
eZSURE™ Empty Fluid Container

Indications for Use *(Describe)*
The Empty Fluid Container is used to hold an admixture of compatible fluids for intravenous administration to a patient. Medication transfer in and out of the container is done using aseptic technique.

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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K252094 – 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 1, 2025
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K252094
Trade/ Device Name:	eZSURE™ *Empty Fluid Container*
Common/ Usual Name:	Empty I.V. bag
Regulation Number:	I.V. container
Regulation Name:	21 CFR 880.5025
Regulatory Class:	Class: II
Product Code:	KPE, ONB

III. Predicate

510(k) Number:	K223674	K241442
Trade/ Device Name:	eZSURE™ *Empty Fluid Container* (models 426030, 426040, 426110)	eZSURE™ *Empty Fluid Container with ProSeal™ Injection Site*
Common/ Usual Name:	Empty I.V. bag	Empty I.V. bag
Regulation Number:	I.V. container	I.V. container
Regulation Name:	21 CFR 880.5025	21 CFR 880.5025
Regulatory Class:	Class: II	Class: II
Product Code:	KPE	KPE, ONB

IV. Purpose of Submission and Device Description

The **eZSURE™** ***Empty Fluid Container (EFC)*** is a sterile, nonpyrogenic, single-use intravenous (IV) bag constructed from flexible, non-PVC film. It is designed for the preparation and administration of IV fluids and is intended for disposal after a single use.

Two previously cleared subgroups include:

- **eZSURE™** ***EFC with Needle-Free Valve (NFV)*** **Additive Port** (K223674)
- **eZSURE™** ***EFC with*** **ProSeal™** ***Injection Site*** **Additive Port** (K241442)

Both subgroups are currently available in **100 mL, 250 mL, and 500 mL** capacities. This Submission introduces a new **1,000 mL** capacity option for each subgroup.

Each *EFC* consists of a flexible plastic film bag with two (2) ports:

- **Additive (filling) port** – for introducing compatible fluids
- **Spiking (administration/access) port** – for accessing the infusate using a standard IV spike

The ***NFV*** **model** features a self-sealing needle-free valve additive port compatible with male Luer lock syringes. The ***Injection Site*** **model** incorporates a *closed-system injection site* with a double elastomeric membrane, compatible with the ProSeal™ *Injector*, which is also compatible with male Luer lock syringes. Both configurations support secure medication addition and maintain a sealed system after device removal.

V. *Indications for Use* Statement

The Empty Fluid Container is used to hold an admixture of compatible fluids for intravenous administration to a patient. Medication transfer in and out of the container is done using aseptic technique.

VI. Comparison of *Intended Use* & *Technological Characteristics*

The Subject devices and the Predicate devices share the following characteristics:

Intended Use **comparison**

There was no difference that would alter the overall intended use of the Subject devices, compared to the Predicate devices, with respect to:

1) *Indications for use* statements
2) Intended user population/ intended use environment
3) Intended drug type
4) Prescription use or over-the-counter use
5) IV bag access components

Technological Characteristics **comparison**

Equivalencies – Technology & Design

The Subject and Predicate devices exhibit the same design characteristics, with their respective filling port types. No substantial differences were identified that would raise concerns regarding safety or performance. The shared characteristics are listed below:

1) Principles of operation
2) Technology and design of the empty container
3) Material of empty container body
4) Materials of additive (filling) port (per type vs. the respective Predicate device)
5) Intended filling device (per type vs. the respective Predicate device)
6) Material of spiking (administration) port
7) Biocompatibility
8) Primary package top & bottom webs
9) Sterilization process
10) Shelf-life validation
11) Single-use or reusable
12) Labeling specifications

There were no substantial differences compared to the Predicate devices listed in **Table 1** and **Table 2**. The respective evaluations – summarized in the respective **Submitter's Comment** at the bottom row of each table – concluded that the identified difference does not pose any safety or performance concerns for either device

Table 1: Comparison of characteristics for eZSURE™ *Empty Fluid Container* (*with NFV filling port*)

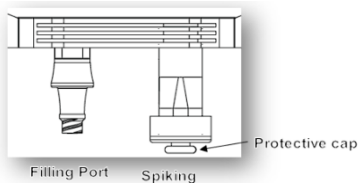
Characteristics compared		**Predicate Device (K223674)** **eZSURE™ *Empty Fluid Container* (*with NFV filling port*)**	**Subject Device (K252094)** **eZSURE™ *Empty Fluid Container* (*with NFV filling port*)**	**Comparative evaluation**
Intended use and *Indications for Use* statement		The Empty Fluid Container is used to hold an admixture of compatible fluids for intravenous administration to a patient. Medication transfer in and out of the container is done using aseptic technique.		Same
Intended user population		Adequately trained health care professionals or pharmacists		Same
Intended use environment		Clinical setting		Same
Intended drug type		Parenteral drugs		Same
Prescription use or over-the-counter use		R only		Same
IV bag access components		Device has 2 access points: 1. Additive port/filling port 2. Spiking/administration/access port, IV spike bag access for IV set/IV line		Same
Principles of operation	*NFV filling port*	The empty bags are filled by connecting transfer devices, e.g., through standard male Luer lock syringes (without needle) or automated filling devices The additive port is a self-sealing **needle-free female luer lock connector**, no different from standard needle-free filling port devices of market-cleared IV sets. **Silicone valve** of the additive port self-seals/re-seals when mating component devices are disconnected from one another. 		Same
	Spiking (administration/ access) port	IV set or IV line is attached through the spiking (administration) port to dispense IV therapy using a standard spike and tubing		Same

Table 1: Comparison of characteristics for eZSURE™ *Empty Fluid Container* (*with NFV filling port*)

Characteristics compared	Predicate Device (K223674)	Subject Device (K252094)	Comparative evaluation
	eZSURE™ *Empty Fluid Container* (*with NFV filling port*)	eZSURE™ *Empty Fluid Container* (*with NFV filling port*)	
Technology and design of the empty container	The bag is manufactured by welding a plastic attachment to the bag body and assembling the bottom with entry and exit connectors/ ports		Same
Material of empty fluid container body	Sealed Air Corp's Medical Packaging Film, Nexcel® Film, Grade M315, Polyolefin		Same
Materials of additive (filling) port	Polypropylene, Polycarbonate, Liquid Silicone Rubber		Same
Intended filling device	Syringe or transfer device with Male Luer lock tip		Same
Material of spiking (administration) port	Thermoplastic elastomer		Same
Maximum volumes	100 mL, 200 mL, 500 mL	1,000 mL	Different see **Comment #1**
Biocompatibility	Acceptable biological risks established by demonstrating that the device meets ISO 10993-1		Same
Primary package top & bottom webs	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
Single use or reusable	Single use only		Same
Labeling specifications	Met the requirements specified in 21 CFR 801		Same

Submitter's Comment (Table 1)
Comment #1
Subject device is different from the Predicate device in its maximum volume capacity. The difference between the Subject device and Predicate device did not raise different questions of safety and effectiveness as functional testing have been conducted and their data are summarized in **section VII.A**. The difference was determined to be insignificant as performance results were determined to have met the intended use. The biocompatibility testing and chemical characterization as well as risk analysis data on cleared device were evaluated for the Subject device and are summarized in **section VII.B**. The difference was determined to be insignificant as results were determined to have met the device's biological safety specifications

Table 2: Comparison of characteristic for eZSURE™ *Empty Fluid Container* (*with* ProSeal™ *Injection Site*)

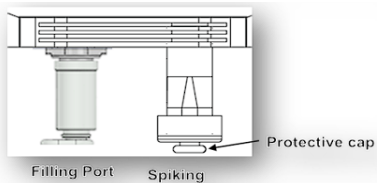
Characteristics compared		Predicate Device (K241442) eZSURE™ *Empty Fluid Container* (*with* ProSeal™ *Injection Site*)	Subject Device (K252094) eZSURE™ *Empty Fluid Container* (*with* ProSeal™ *Injection Site*)	Comparative evaluation
Intended use and *Indications for Use* statement		The Empty Fluid Container is used to hold an admixture of compatible fluids for intravenous administration to a patient. Medication transfer in and out of the container is done using aseptic technique.		Same
Intended user population		Adequately trained health care professionals or pharmacists		Same
Intended use environment		Clinical setting		Same
Intended drug type		Parenteral drugs		Same
Prescription use or over-the-counter use		℞ only		Same
IV bag access components		Device has 2 access points: 1. Additive port/filling port 2. Spiking/administration/access port, IV spike bag access for IV set/IV line		Same
Principles of operation	*Injection site filling port*	The empty bags are filled by connecting transfer devices, e.g., through standard male Luer lock syringes (without needle) or automated filling devices, attached to the ProSeal™ *Injector*. The additive port is a self-sealing **closed system ProSeal™ *Injection Site.*** **Membrane** of the additive port self-seals/re-seals when mating component devices are disconnected from one another. 		Same
	Spiking (administration/ access) port	IV set or IV line is attached through the spiking (administration) port to dispense IV therapy using a standard spike and tubing		Same
Technology and design of the empty container		The bag is manufactured by welding a plastic attachment to the bag body and assembling the bottom with entry and exit connectors/ ports		Same

Table 2: Comparison of characteristic for eZSURE™ *Empty Fluid Container* (*with* ProSeal™ *Injection Site*)

Characteristics compared	Predicate Device (K241442)	Subject Device (K252094)	Comparative evaluation
	eZSURE™ *Empty Fluid Container* (*with* ProSeal™ *Injection Site*)	eZSURE™ *Empty Fluid Container* (*with* ProSeal™ *Injection Site*)	
Material of empty fluid container body	Sealed Air Corp's Medical Packaging Film, Nexcel® Film, Grade M315, Polyolefin		Same
Materials of additive (filling) port	Polypropylene, Polyisoprene Rubber (IR)		Same
Intended filling device	ProSeal™ *Injector or* ProSeal™ *Injector Plus* (cleared K241071) Male Luer Lock tip		Same
Material of spiking (administration) port	Thermoplastic elastomer		Same
Maximum volumes	100 mL, 200 mL, 500 mL	1,000 mL	Different see **Comment #1**
Biocompatibility	Acceptable biological risks established by demonstrating that the device meets ISO 10993-1		Same
Primary package top & bottom webs	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
Single use or reusable	Single use only		Same
Labeling specifications	Met the requirements specified in 21 CFR 801		Same

Submitter's Comment (Table 2)
Comment #1
Subject device is different from the Predicate device in its maximum volume capacity. The difference between the Subject device and Predicate device did not raise different questions of safety and effectiveness as functional testing have been conducted and their data are summarized in **section VII.A**. The difference was determined to be insignificant as performance results were determined to have met the intended use. The biocompatibility testing and chemical characterization as well as risk analysis data on cleared device were evaluated for the Subject device and are summarized in **section VII.B**. The difference was determined to be insignificant as results were determined to have met the device's biological safety specifications

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The Subject device was evaluated to be in conformance with the following ANSI/AAMI and ISO standards, and the product code-applicable FDA guidance document:

- **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 15747:2018**, *Plastic containers for intravenous injections*
- **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***

Bench performance verifications and validations were performed on the Subject device and leveraged from the relevant testing data from the Predicate devices and the existing device: K223674/S001, K241442 and K230343/S001:

On Subject device

- **Resistance to temperature, pressure and fluid leakage tests** per ISO 15747:2018, Annex A.3
- **Accelerated aging tests** per ASTM F1980-21 of above tests
- **Resistance to dropping test** per ISO 15747:2018, Annex A.4
- **Accelerated aging test** per ASTM F1980-21 of above test
- **Hanger tensile strength test** per ISO 15747:2018, Annex A.11
- **Accelerated aging tests** per ASTM F1980-21 of above tests

Under K223674 – NFV filling port version

- **Infusion container transparency test** to ISO 15747:2018
- **Water vapor impermeability test** to ISO 15747:2018
- **Access port cover test** to ISO 15747:2018
- **Access port penetration ability of insertion point test** to ISO 15747:2018
- **Access port adhesion strength of infusion device and impermeability of the insertion point test** to ISO 15747:2018
- **Access port liquid tightness of the insertion point test t**o ISO 15747:2018
- **Identification test** to ISO 15747:2018
- **Requirements for the raw container and test fluids test** to ISO 15747:2018
- **Impermeability to microorganism and migration test** to ISO 15747:2018
- **7-day microbial ingress test** per FDA guidance and AAMI CN27:2021

Under K241442 - Injection Site filling port version

- **Additive port air and liquid tightness test** to ISO 15747:2018
- **Impermeability to microorganism test** to ISO 15747:2018

Under K240433 - Injection Site filling port version

- **Additive port positive pressure fluid leakage test** to ISO 80369-7:2021
- **Sub-atmospheric pressure air leakage test** to ISO 80369-7:2021
- **Stress cracking test** to ISO 80369-7:2021
- **Resistance to separation from axial load test** to ISO 80369-7:2021
- **Resistance to separation from unscrewing test** to ISO 80369-7:2021
- **Resistance to overriding** to ISO 80369-7:2021
- **Device leakage integrity test** to ISO 8536-4:2019
- **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 Subject device is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were conducted under the Predicate devices and the existing device: K223674/S001, K241442, K240433; and the Subject device:

- **Cytotoxicity** per ISO 10993-5:2009
- **Sensitization** per ISO 10993-10:2010
- **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
- **Material mediated pyrogenicity** per ISO 10993-11:2017
- **Chemical characterization and toxicological risk assessment** per ISO 10993-18:2020 & ISO 10993-17:2002
- **Particulate matter testing** per ISO 15747:2018, *Plastic containers for intravenous injections* and USP <788> *Particulate Matter in Injections*, on the Predicate devices and on the Subject device
- **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 special patient population, as defined by the amended standard's patient population categories on the Subject device

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:

- **Simulated shipping testing** per ASTM D 4169-16*, Standard Practice for Performance Testing of Shipping Containers and Systems* under K151650/S004 and K223674/S001
- **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

The difference between the Predicate and the Subject device does not raise any new or different questions of safety or effectiveness. The **eZSURE™ *Empty Fluid Container (EFC)*** is substantially equivalent to the **Predicate devices (K223674 & K241442)** in all aspects