June 21, 2024

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

Re: K241442
Trade/Device Name: eZSURE™ Empty Fluid Container with ProSeal™ Injection Site
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: Class II
Product Code: KPE, ONB
Dated: May 22, 2024
Received: May 22, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241442

Device Name
eZSURE™ Empty Fluid Container with ProSeal™ Injection Site

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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K241442 – 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: June 20, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K241442
Proprietary/ Trade/ Device Name:	**eZSURE™ Empty Fluid Container with ProSeal™ Injection Site**
Common/Usual/Generic Name:	Empty I.V. bag
Classification Name/ Regulation Name:	I.V. container
Device Classification Regulation Number:	21 CFR 880.5025
Regulatory/ Device Class:	Class: II
Classification Product Code:	KPE (primary) and ONB (secondary)

III. Predicate

510(k) Number:	K223674
Proprietary/ Trade/ Device Name:	**eZSURE™ Empty Fluid Container** (models 426030, 426040, 426110)
Common/Usual/Generic Name:	Empty I.V. bag
Classification Name/ Regulation Name/ Description:	I.V. container
Device Classification Regulation Number:	21 CFR 880.5025
Classification Product Code:	KPE
Regulatory/ Device Class:	Class: II

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 the **existing eZSURE™ *Empty Fluid Container*** — the **Subject eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site***. This device is an addition to the ProSeal™ *CSTD* system of devices (cleared K240433). The existing device, and also the nominated Predicate device, is the eZSURE™ *Empty Fluid Container* (cleared K223674).

The eZSURE™ *Empty Fluid Container (EFC)* devices are empty single-use, sterile, nonpyrogenic flexible IV container devices/ bags. These are discarded after use. The Subject *EFC* is made of non-PVC materials. The Nexcel Film for IV bag of the Subject *EFC* device is composed of a flexible plastic film bag and the device is provided in a two-port configuration with closures.

A closed system inlet-/ entry-/ additive- port is used for filling one or more compatible fluid(s) into the bag by a transfer set/ syringe without needle with the ProSeal™ *Injector* or ProSeal™ *Injector Plus* (cleared K240171) attached, and another port, the spiking/ administration port, is used for accessing the infusate in the bag with a standard bag spike in an IV therapy administration from the *EFC*. The transfer device with a male Luer lock attached with the ProSeal™ *Injector* (or ProSeal™ *Injector Plus*) is used to connect to the filling-/ additive- port for filling. The additive port incorporates a ProSeal™ *Injection Site* (cleared K240433) as its integrated subcomponent; hence no other injection needle/ cannula is needed. The transfer device is removed at the end of the preparation step, and the self-sealing additive-/ injection-/ filling- port secures the admixture contents until their administration.

The closed transfer of liquid that takes place with the use of the ProSeal™ *CSTD* system (K240433) as follows:

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

For administration to a patient, the device is then connected to an external IV set /IV line, via a bag spike. The IV bag is piped by inserting the spike point of a bag spike into the spiking-/administration- port of the IV bag, doing this by performing a twisting motion. When the bag is already filled, other medications can be added using the additive/ injection/ filling port, even during administration. Medication transfer in and out of the container is done using aseptic technique. The bags range in volume capacities of 100 mL, 250 mL, and 500 mL.

The *EFC* sub-components are externally communicating devices with no contact to the blood path. Contact duration is categorized as B-prolonged, (>24h to 30d), per ISO 10993-1: 2018 biocompatibility guidelines.

The only modification proposed in this Submission is the change of the fill port design from the needle free valve to the ProSeal™ *Injection Site* (cleared K240433).

The modified and existing device have the same intended use, and the ProSeal™ *Injection Site* is a cleared CSTD component device (K220433). The principles of operation, indications for use statement, and the user-applications remain the same.

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 Technological Characteristics

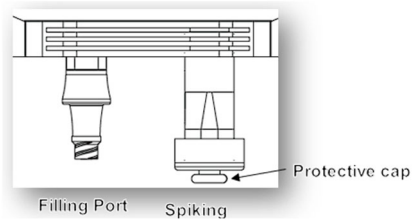
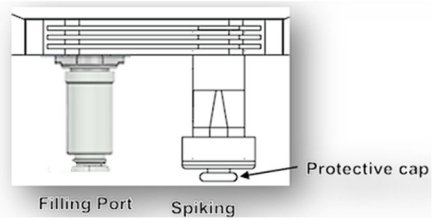
The Subject device and the Predicate device share the following key characteristics:

- Same 2-port configuration - an additive/ filling port and a spiking/ administration port
- Same basic design features - clear, flexible, and empty IV fluid bag that allows for preparation and administration of IV therapies
- Same means of attachment provided for an IV administration set/ line, for the delivery of IV therapy

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

Characteristic compared	**Predicate Device** eZSURE™ *Empty Fluid Container* (K223674)	**Subject Device** eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241442)	**Comment/ Discussion**
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."	"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
Primary product code and regulation number	KPE 21 CFR 880.5025	KPE 21 CFR 880.5025	Same
Intended user population/ intended use environment	Adequately trained health care professionals or pharmacists/ clinical setting	Adequately trained health care professionals or pharmacists/ clinical setting	Same
IV bag components/ access components	Device has 2 access points: 1. Additive port/ filling port 2. Spiking/ administration port, IV spike bag access for IV set/ IV line	Device has 2 access points: 1. Additive port/ filling port 2. Spiking/ administration port, IV spike bag access for IV set/ IV line	Same

Characteristic compared	**<u>Predicate Device</u>** eZSURE™ *Empty Fluid Container* (K223674)	**<u>Subject Device</u>** eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241442)	**Comment/ Discussion**
System component devices	1. ProSeal™ *Injector* (model 421010) (K240433) 2. ProSeal™ *Injector Plus* (model 421050) (K240433) 3. ProSeal™ *Connector* (model 422010) (K240433) 4. ProSeal™ *Injection Site Extended Male Luer Lock* (K240433) 5. ProSeal™ *Vial Adaptor* (3 models 4200X0, for options of vial neck sizes and pressure equalizations) (K240433) 6. ToxiSeal™ *Vial Adaptor with External Balloon* (K222929) 7. ProSeal™ *Assembly Fixture* (Fixture for ProSeal™ *Vial Adaptor* assembly, model 424010) (K240433)	1. ProSeal™ *Injector* (model 421010) (K240433) 2. ProSeal™ *Injector Plus* (model 421050) (K240433) 3. ProSeal™ *Connector* (422010) (K240433) 4. ProSeal™ *Injection Site Extended Male Luer Lock* (K240433) 5. ProSeal™ *Vial Adaptor* (3 models 4200X0, for options of vial neck sizes and pressure equalizations) K240433) 6. ToxiSeal™ *Vial Adaptor with External Balloon* (K222929) 7. ProSeal™ *Assembly Fixture* (Fixture for ProSeal™ *Vial Adaptor* assembly, model 424010) (K240433) 8. **eZSURE™ *Empty Fluid Container with ProSeal™ Injection Site* ((K241442) the Subject device)**	Different The Subject system component device **(#8 in the column <u>Subject Device</u>)**, is an addition to the existing seven (7) component devices of ProSeal™ *CSTD* (K240433) and the ToxiSeal™ *Vial Adaptor with External Balloon* (K222929), indicated in **bold face texts.** Differences are addressed in **Discussion of differences in technological characteristics**: **Comments #1** and **#2** under this table, on **page 8**.
Intended drℓ type	Parenteral drugs	Parenteral drugs	Same
Rℓ/ Prescription use	Rℓ only	Rℓ only	Same

Characteristic compared	**Predicate Device** eZSURE™ *Empty Fluid Container* (K223674)	**Subject Device** eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241442)	Comment/ Discussion
Principles of operation	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 injection site 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 	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* (or the ProSeal™ *Injector Plus*)** 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 	Different See **Comment #1**
	IV set/ IV line is attached through the spiking/ administration port to dispense IV therapy using a standard spike and tubing	IV set/ IV line is attached through the spiking/ administration port to dispense IV therapy using a standard spike and tubing	Same
Technology and design	The bag is manufactured by welding a plastic attachment to the bag body and assembling the bottom with entry and exit connectors/ ports	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	Sealed Air Corp's Medical Packaging Film, Nexcel® Film, Grade M315, Polyolefin	Same

Characteristic compared	**Predicate Device** eZSURE™ *Empty Fluid Container* (K223674)	**Subject Device** eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site* (K241442)	**Comment/ Discussion**
Material of additive filling port	Polypropylene, **Polycarbonate, Liquid Silicone Rubber**	Polypropylene, **Polyisoprene Rubber (IR)**	Different See **Comment #1**
Material of spiking/ administration port	Thermoplastic elastomer	Thermoplastic elastomer	Same
Intended Injector for filling the empty fluid container	ProSeal™ *Injector* (model 421010) (cleared K192075) Male Luer Lock tip	ProSeal™ *Injector* (model 421010) or **ProSeal™ *Injector Plus* (model 421050) (cleared K241071)** both Male Luer Lock tip	Different **See Comment #2**
Primary package top web	Medical grade paper and medical plastic film, heat sealed	Medical grade paper and medical plastic film, heat sealed	Same
Sterilization method	Ethylene Oxide, EO, SAL 10^{-6}	Ethylene Oxide, EO, SAL 10^{-6}	Same
Validated Shelf life	3 years (36 months)	3 years (36 months)	Same
Reuse or single-use	Single-use only	Single-use only	Same
Labeling specifications	Meets the requirements specified in 21 CFR 801	Meets the requirements specified in 21 CFR 801	Same

Discussion of differences in technological characteristics

Comment #1

The membrane material of Subject device's closed system ProSeal™ *Injection Site Extended Male Luer Lock* (model 422140) (ProSeal™ *Injection Site*) is made of polyisoprene rubber (IR), the same as the IR present in Epic Medical Pte Ltd's cleared K240433, ProSeal™ *Injection Site*, in the same design configuration and it had been biologically evaluated to have conformed with ISO 10993-1: 2018. Therefore, biocompatibility testing was leveraged from K240433. Moreover, the functional performance of the assembled ProSeal™ *Injection Site* in the Subject device, had been adequately evaluated and as such, performance testing was leveraged form K240443. In additional bench top performance verification testing of the subject device over the shelf life was conducted to the standards listed in section VII.A second paragraph, hereunder, to demonstrate that the difference in technological characteristics do not raise different questions of safety and effectiveness.

Comment #2

The 2024-03-28 cleared ProSeal™ *Injector Plus* (cleared K240171), a modified version of ProSeal™ *Injector*, is another option of an *Injector* available for users to use with the Subject *Empty Fluid Container* devices. This difference does not raise new questions of safety and effectiveness of the Subject device.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The sterile, single-use, non-pyrogenic flexible IV container devices/ bags described in this Summary were evaluated to be in conformance with the following ISO and FDA recognized standards:

- 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*

Bench performance verifications and validations performed on the Subject device:

- Resistance to Temperature, Pressure and Leakage test to ISO 15747 on the Subject device
- Resistance to Dropping test to ISO 15747 on the Subject device
- Additive Port Liquid Tightness (Air and Liquid Leakages) test to ISO 15747 on the Subject device
- Impermeability to Microorganism test to ISO 15747 on the Subject device

The ProSeal™ *Injection Site* (cleared K240433) incorporated as the Subject device's integrated additive port, described in section IV in this Summary, and its IR membrane subcomponent part, were tested and demonstrated to be in conformance with the following ISO and FDA recognized standards and FDA guidance document:

- ISO 8536-4: 2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 80369-7: 2016, *Small-bore connectors for liquids and gases in healthcare application - Part 7, Connectors for intravascular or hypodermic applications*
- *US FDA Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)], Issued on July 11, 2008*

Bench performance verifications and validations were performed on clearance of the ProSeal™ *Injection Site,* cleared under K240433 incorporated in the Subject device's additive port:

- Positive pressure fluid leakage test
- Sub-atmospheric pressure air leakage test
- Stress cracking test
- Resistance to separation from axial load test
- Resistance to separation from unscrewing test
- Resistance to overriding
- Device leakage integrity test
- 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, just like the existing device, is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing are referred to, from testing data on the existing devices, cleared, as listed hereunder :

- Cytotoxicity to ISO 10993-5 under K223674 & K240433
- Sensitization to ISO 10993-10 under K223674 & K240433
- Intracutaneous Reactivity to ISO 10993-10 under K223674 & K240433
- Acute Systemic Toxicity to ISO 10993-11 under K223674 & K240433
- 14-day Subacute/ Subchronic Acute Systemic Toxicity to ISO 10993-11 under K223674 & K240433
- In-vitro Hemolysis Assessment to ISO 10993-4 under K223674 & K240433
- Material Mediated Pyrogenicity to ISO 10993-11 under K223674 & K240433
- Chemical Characterization & Toxicological Risk Assessment to ISO 10993-18 & ISO 10993-17 under K223674 & K240433

Particulate matter testing was conducted in accordance with ISO 15747: 2018, *Plastic containers for intravenous injections* and USP <788> *Particulate Matter in Injections*.

C. Sterility, Shipping, and Shelf-Life

The Subject device, like the existing device cleared under K223674, 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:

- Package Integrity Tests per ASTM F1980-16, *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*, ASTM F1929-15, *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*
- Shelf-life of 3 years has been validated using the FDA recognized standard, ASTM 1980-16, *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, eZSURE™ *Empty Fluid Container with* ProSeal™ *Injection Site*** (fill port) is substantially equivalent to the **Predicate, the eZSURE™ *Empty Fluid Container*** (with needle-free valve fill port), with respect to the indications for use, principles of operation and technological characteristics.