September 1, 2023

Epic Medical Pte Ltd
Freddie Lee
CEO
105 Cecil, 20-01 The Octagon
Singapore, Singapore 069534
Singapore

Re: K223674
Trade/Device Name: eZSURE™ Empty Fluid Container (models 426030, 426040, 426110)
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: Class II
Product Code: KPE
Dated: August 2, 2023
Received: August 2, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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)*
K223674

Device Name
eZSURE™ Empty Fluid Container (models 426030, 426040, 426110)

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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K223674- 510(k) Summary

I. Submitter

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Phone: +65 9635 2618 / +66 81 761 5292

Contact Person: Mr. Freddie LEE, Chief Executive Officer/ Managing Director
Date Prepared: September 1, 2023

II. Subject Device

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

III. Predicate Device

510(k) Number:	K181393
Proprietary/Trade Name:	Empty EVA Bag (models FVM0134BP, FVM0135BP, FVM0136BP, FVM0137BP, FVM0138BP, FVM0139BP, FVM0140BP, FVM0141BP)
Common /Usual Name:	Empty I.V. bag
Regulation Name:	I.V. Container
Product Code:	KPE
Regulation Number:	21 CFR 880.5025
Device Class:	Class: II

IV. Device Description

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 device is composed of a flexible plastic film bag and two separate ports with closures, one for injection and another, infusion. An inlet-/ entry-/ additive- port is used for filling one or more compatible fluid(s) into the bag by a transfer set/ syringe without needle, and another port, the spiking/ administration port, is used for accessing the infusate in the bag with a standard bag spike. A transfer device with a male luer lock is used to connect to the filling-/ additive- port for filling. The additive port incorporates a needle-free valve; hence no injection needle/ cannula is needed. The transfer device is removed at the end of the preparation step, and the needle-free self-sealing additive-/ injection-/ filling- port secures the admixture contents until their administration.

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 capacity of 100 mL, 250 mL, and 500 mL. The device has a hanger hole so it can be placed on an IV bag holder.

The EFC is made of non-PVC materials and provided in a two-port configuration: The needle free additive port which is used for filling the container and the other, the spiking-/ administration port, which is used for IV therapy administration from the EFC. The EFC sub-components are externally communicating devices with no contact to the blood path. The contact duration is categorized as B-prolonged, (>24h to 30d), per ISO 10993-1 :2018 biocompatibility guidelines.

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 eZSURE™ Empty Fluid Container devices and the Predicate devices share the following characteristics:

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

The overview table hereunder compares parameters between the Subject and Predicate devices.

Parameter compared	**Predicate Device** Empty EVA Bag (K181393)	**Subject Device** eZSURE™ Empty Fluid Container (EFC) (K223674)	**Comment/ Discussion**
Indications for Use statement	"The Empty EVA Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. 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 as Predicate Both devices are intended for and indicated for the use in holding admixture fluids/IV solutions for the subsequent administration/ transfer of the IV solutions from the container to an external IV administration set/ line, working in combination, complementarily, applying aseptic technique
Product code and regulation number	KPE, 21 CFR 880.5025	KPE, 21 CFR 880.5025	Same as Predicate
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 as Predicate
IV drug component bag components/ access components	Empty EVA Bag, has 2 access points: 1. Additive port/ filling port 2. Spiking/ administration port, IV spike bag access for IV set/ IV line	eZSURE™ EFC, has 2 access points: 1. Additive port/ filling port 2. Spiking/ administration port, IV spike bag access for IV set/ IV line	Same as Predicate
Intended drug type(s)	Parenteral drugs	Parenteral drugs	Same as Predicate
Rx/ Prescription Use	℞ only	℞ only	Same as Predicate

Parameter compared	**Predicate Device** Empty EVA Bag (K181393)	**Subject Device** eZSURE™ Empty Fluid Container (EFC) (K223674)	**Comment/ Discussion**
Principles of operation	The empty bags are filled by connecting to containers containing one or more solutions, e.g., through standard syringes or automated filling devices After filling, the bags are clamped to secure the contents prior to administration. IV set/ IV line is attached through the spiking/ administration port to dispense IV therapy using a standard spike and tubing	The empty bags are filled by connecting to containers containing one or more solutions, e.g., through standard 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 IV set/ IV line is attached through the spiking/ administration port to dispense IV therapy using a standard spike and tubing	Different, but Substantially Equivalent to Predicate: Both the Subject device and the Predicate device comprise two ports – the additive port and the spiking/ administration port. Both the Subject devices and Predicate devices are bulk-filled by the user through the additive port. Subject devices allow additional-filling through the additive port, whereas the additive/ filling port on the Predicate device is designed to be used to filled once and clamped with inviolable clamp after filling Both the Subject device and Predicate device comprise a spiking/ administration port to connect an IV administration set/ line for the delivery of IV therapy to the patient Both the Subject and Predicate devices provide a mechanism for safe filling of the bag and the administration of IV therapy to the patient using an IV administration set/ line. Performance testing of the subject device demonstrates that the differences do not raise new or different questions of safety and effectiveness.

Parameter compared	**Predicate Device** Empty EVA Bag (K181393)	**Subject Device** eZSURE™ Empty Fluid Container (EFC) (K223674)	**Comment/ Discussion**
Technology and design	The EVA bag device includes an administration port and an additive port. The administration port provides a connection to the IV set/ line. The additive port is a connector by which medications can be added to the bag/ container using the medication port before IV administration. A capsule closes the medication port after use. The bags/ containers are clamped after filling by the means of inviolable clamps An IV set/ IV line is connected to the fluid container/ bag to dispense IV therapy	The EFC device includes an administration port and an additive port. The administration port provides a connection to the IV set/ line. The additive port, a needle-free female luer lock connector, like the injection sites of other market- cleared IV sets, allows for medication(s) to be added to the bag/container prior to and during IV administration. Silicone valve of the additive port self-seals/ re- seals when mating component devices are disconnected from one another An IV set/ IV line is connected to the fluid container/ bag to dispense IV therapy	Different, but Equivalent to Predicate: Though a difference in securing the fluid container content after being filled – silicone valve of the sterile additive port self-seals/ re-seals when mating component devices are disconnected from one another in the case of the Subject device. This contrasts with the Predicate device in which the user clamps the port after filling by means of an inviolable clamp. Performance testing of the subject device demonstrates that the differences do not raise new or different questions of safety and effectiveness.
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 as Predicate

Parameter compared	**Predicate Device** Empty EVA Bag (K181393)	**Subject Device** eZSURE™ Empty Fluid Container (EFC) (K223674)	**Comment/ Discussion**
Material of empty fluid container body	Ethylene-vinyl acetate (EVA)	Sealed Air Corp's Medical Packaging Film, Nexcel® Film, Grade M315, Polyolefin	Different, but Substantially Equivalent to Predicate: Though a difference in the material used to build the fluid container main body exists, it did not raise additional questions of safety or of performance effectiveness. This is because both materials are highly transparent clear, flexible plastic film formulated for its intended use as primary medical film for bag body of medical IV bags - free of PVC, plasticizers, adhesives, latex - that could potentially leach into certain solutions, and both are suitable for EO sterilization Performance, shelf life, and biocompatibility testing of the subject device demonstrates that the differences do not raise new or different questions of safety and effectiveness.
Materials of additive/ filling port	Polyisoprene, Polypropylene Acrylonitrile Butadiene Styrene	Polypropylene Polycarbonate Liquid Silicone Rubber	Different, but Substantially Equivalent to Predicate: Though a difference in the materials used for the additive port exists, it did not raise additional questions of safety or of performance effectiveness. The valve material, Silicone, QP1-30, is an USP (U.S. Pharmacopoeia) class VI elastomer silicone rubber that does not contain phthalates nor latex

Parameter compared	**Predicate Device** Empty EVA Bag (K181393)	**Subject Device** eZSURE™ Empty Fluid Container (EFC) (K223674)	**Comment/ Discussion**
			additives. It is recommended for medical devices including those implanted in humans for less than 30 days besides non-implant applications Performance, shelf life, and biocompatibility testing of the subject device demonstrates that the differences do not raise new or different questions of safety and effectiveness.
Material of spiking/ administration port	PVC not made with DEHP	Thermoplastic elastomer	Different, but Equivalent to Predicate.: Though a difference in the materials used for the spiking/ administration port exists, it did not raise additional questions of safety or of performance effectiveness. This is because eZSURE™ EFC does not use PVC, not even those not made with plasticizer DEHP - that could potentially leach into certain solutions. Performance, shelf life, and biocompatibility testing of the subject device demonstrates that the differences do not raise new or different questions of safety and effectiveness.
Biocompatibility	Acceptable biological risks established by demonstrating that the device meets ISO 10993-1	Acceptable biological risks established by demonstrating that the device meets ISO 10993-1	Same as Predicate
Sterilization method	Ethylene Oxide, EO, SAL 10^{-6}	Ethylene Oxide, EO, SAL 10^{-6}	Same as Predicate

Parameter compared	**Predicate Device** Empty EVA Bag (K181393)	**Subject Device** eZSURE™ Empty Fluid Container (EFC) (K223674)	**Comment/ Discussion**
Shelf life	3 years (36 months)	5 years	Different, but Equivalent to Predicate: Device performance and shelf-life testing of the subject device demonstrates that the differences do not raise new or different questions of safety and effectiveness.
Reuse or single-use	Single-use only	Single-use only	Same as Predicate
Primary package top web	Medical grade paper and medical plastic film, heat sealed	Medical grade paper and medical plastic film, heat sealed	Same as Predicate

Discussion of differences in technological characteristics

The preceding table summarizes the technological comparisons between the eZSURE™ EFC and the Predicate devices identifying differences in materials of construction: a) empty fluid container body, b) additive/ filling port and c) administration port. Although the Subject devices contain differences in material composition compared to the Predicate devices, these differences between the Subject and Predicate devices were evaluated and do not raise new questions of safety and effectiveness. These differences were further addressed and evaluated for safety and effectiveness through non-clinical performance testing, biocompatibility evaluation and sterilization and shelf-life studies, and summarized in VII below. The outcome of the evaluation and testing demonstrates that data within this submission support that the eZSURE™ Empty Fluid Container devices are substantially equivalent to the Submitter designated Predicate devices in terms of safety and performance effectiveness.

VII. Performance Data Supporting Substantial Equivalence

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

- ANSI/AAMI CN27:2021, *General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications*
- ANSI/AAMI ST72/ 2019, *Bacterial endotoxins – Test methods, routing monitoring, and alternatives to batch testing*
- ASTM F1929-15, *Standard test method for detecting seal leaks in porous medical device packaging by dye penetrati*on
- ASTM F1980-16, *Standard guide for accelerated aging of sterile barrier systems for medical devices*
- 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*
- ISO 15747: 2018, *Plastic containers for intravenous injections*
- ISO 22413: 2021, *Transfer sets for pharmaceutical preparations – Requirements and test methods*
- ISO 8536-4: 2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- USP 40 <151>, *Pyrogen test (USP rabbit test)*
- USP-NF <161>, *Medical Devices-Bacterial Endotoxin and Pyrogen Tests*
- USP-NF <85>, *Bacterial Endotoxins Test*

Testing done:

- Resistance to Temperature, Pressure and Leakage
- Resistance to Dropping
- Water Vapor Impermeability
- Spiking Port Penetration Ability
- Spiking Port Adhesion Strength
- Additive Port Liquid Tightness
- Hanger Tensile Strength
- Identification Clarity
- Particulate Non-contamination
- Impermeability to Microorganism
- 7-day Microbial Ingress Test

B. Biocompatibility

In accordance with ISO 10993-1: 2018, the ToxiSeal™ *Vial Adaptor with External Balloon* is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The biological safety and biocompatibility were evaluated, and found to have met their respective acceptance criteria.

Conclusion to the biological evaluation of the eZSURE™ Empty Fluid Container was that upon completing the evaluation according to ISO 10993-1:2018, the results demonstrated that the eZSURE™ EFC met the biological safety and biocompatibility requirements when used as intended.

Particulate matter testing was conducted in accordance with ISO 15747: 2018, *Plastic containers for intravenous injections* and USP <788> *Particulate Matter in Injections* and found to have met the ISO and USP acceptance criteria.

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.*

- Package Integrity Test
- Sterile Barrier Packaging Testing performed on the proposed device: Seal strength – ASTM F88
- 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. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The eZSURE™ EFC is substantially equivalent to the predicate, Empty EVA Bag, with respect to the indications for use, principles of operation and technological characteristics.