June 12, 2026

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

Re: K252987
Trade/Device Name: ADRx™ Admixture Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: LHI
Dated: May 13, 2026
Received: May 13, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*
K252987

Device Name
ADRx™ Admixture Device

Indications for Use *(Describe)*
The ADRx™ Admixture Device is intended to connect an IV bag, a drug vial, and a standard external IV administration set. It facilitates the safe reconstitution of drug vials using diluents from the IV bag and enables the transfer of vial contents into the IV bag prior to patient administration.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K252987 – 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 11, 2026
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Traditional 510(k)

II. Subject Device

510(k) Number:	K252987
Trade/ Device Name:	ADRx™ *Admixture Device*
Common/ Usual Name:	Set, I.V. Fluid Transfer
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set.
Regulatory Class:	Class: II
Product Code:	LHI

III. Predicate

510(k) Number:	K201415
Trade/ Device Name:	Vial2Bag Advance™ *20mm Admixture Device*
Common/ Usual Name:	Set, I.V. Fluid Transfer
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set.
Regulatory Class:	Class: II
Product Code:	LHI

IV. Device Description

The **ADRx™ *Admixture Device*** is a **sterile, single-use adaptor** designed to connect standard I.V. bag and components for the **safe reconstitution and transfer of fluids**. It enables **secure and efficient preparation** and **transfer** of I.V. fluids and drug solutions, supporting **point-of-care mixing and direct bedside administration**.

Device Components and Models:

- **Component Subgroups:**
  - **ADRx™ *SingleDose*:**
    (I.V. bag spike with integrated vial adaptor)
    - An integrated assembly comprising an IV bag spike with spiking port and an attached vial adaptor for drug reconstitution and transfer
    - Designed to support **direct reconstitution and transfer of s single drug dose** from a **13 mm or a 20 mm vial** into I.V. bag, without the need for additional external bag spikes or adaptor components
  - **ADRx™ *UniqDose*:**
    (Standalone vial adaptor derived from the **ADRx™ *SingleDose***, *20 mm configuration)*
    - The **ADRx™ *UniqDose*** consists of the **vial adaptor and vial spike subassembly** of the **ADRx™ *SingleDose*** 20 mm vial configuration, without the integrated IV bag spike and spiking port
    - Designed for use as a **standalone vial adaptor**, enabling drug reconstitution and transfer when directly connected to an IV bag featuring a compatible **Luer access port**, or when used in combination with a separate IV bag spike assembly
    - The **ADRx™ *UniqDose*** retains the same vial interface design, materials, and functional characteristics as the vial adaptor used in the **ADRx™ *SingleDose*** 20 mm model
- **Compliance:**
  - ISO 8536-4:2019
- **Compatibility:**
  - **ADRx™ *SingleDose*** is compatible with 13 mm or 20 mm drug vials that fit its *vial adaptors*, and **ADRx™ *UniqDose***, with 20 mm drug vials
  - Compatible with standard I.V. bags and I.V. administration sets with ISO 8536-4:2019-compliant bag spikes
- **Safety:**
  - Sterile and single-use, single-patient use
  - Dry connections to minimize exposure to contaminants
- **Intended Users:**
  - Health care professionals in clinical settings

V. *Indications for Use* Statement

The **ADRx™** ***Admixture Device*** is intended to connect an IV bag, a drug vial, and a standard external IV administration set. It facilitates the safe reconstitution of drug vials using diluents from the IV bag and enables the transfer of vial contents into the IV bag prior to patient administration.

VI. Comparison of *Intended Use & Technological Characteristics*

The Subject device, **ADRx™** ***Admixture Device***, and the Predicate device, **K201415** – **Vial2Bag Advanced™** ***20 mm Admixture Device*** – share the same intended use and similar technological characteristics. Differences identified have been evaluated through verification testing performed to FDA-recognized standards and do not raise new or different questions of safety and effectiveness.

Intended Use **comparison**

- *Indications for use* statements (similar)
- Prescription use
- Intended user population/intended use environment
- Intended drug type

Technological Characteristics **comparison**

The **ADRx™** ***Admixture Device*** and the Predicate device share key design and performance characteristics. Evaluation confirmed that no differences raise new or different questions of safety or effectiveness:

- Principles of operation
- Bag spike design
- Number of access points
- Biocompatibility of fluid path materials
- Sterile barrier packaging
- Sterilization process
- Shelf-life
- Single use
- Labeling specifications

All differences, including the vial adaptor dimensional variation for 13 mm and 20 mm vial closures, were thoroughly evaluated. A side-by-side comparison of key characteristics between the Subject and the Predicate device is provided in the table below:

Table: Side-by-side comparison of intended use and technology & design

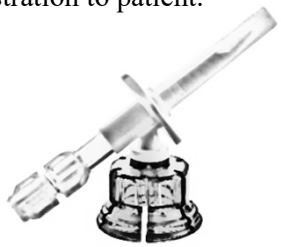
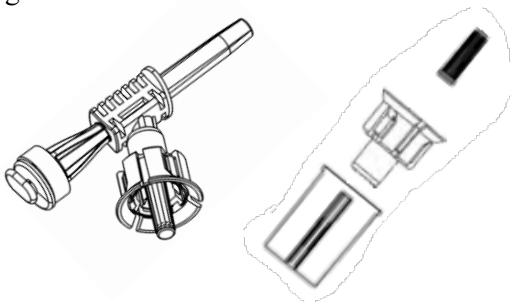
Characteristic compared	Predicate Device (K201415) Vial2Bag Advanced™ *20 mm Admixture Device*	Subject Device (K252987) ADRx™ *Admixture Device*	Comment/ Discussion
Intended use and *Indications for Use* statement	The Vial2Bag Advanced™ *20mm Admixture Device* is **indicated to serve as a connecting part between a 50, 100 or 250mL IV bag, vial with 20mm closure, and an external IV administration set**. The integrated Vial Adaptor makes it possible **to reconstitute and/or admix drugs** prior to administration to the patient.	The ADRx™ *Admixture Device* is **intended to connect an IV bag, a drug vial, and a standard external IV administration set**. It **facilitates the safe reconstitution of drug vials using diluents from the IV bag and enables the transfer of vial contents into the IV bag** prior to patient administration.	Different see **Comment#1**
Prescription use	℞ only		Same
Intended user population/intended use environment	Adequately trained health care professionals including pharmacists/clinical setting		Same
Intended drug type	Parenteral drugs		Same
Principles of operation (except vial closure size)	The Vial2Bag Advanced® *20mm Admixture Device* is operated by manual process. The Vial Adapter is first attached to the drug vial, and after removing the Protector, the IV spike is then connected to the administration port of the IV bag. Fluid is transferred from the IV bag to the drug vial to reconstitute/dilute the drug prior to being transferred back to the IV bag. The IV administration set is then connected to the device's IV Port followed by administration to patient. 	The ADRx™ *SingleDose* and *UniqDose* are intended for health care professionals in various settings such as pharmacies, clinics, emergency departments, hospital wards, ambulances, and pre-hospital care. It serves as a connector between the I.V. bag and an external I.V. line, facilitating the safe and easy reconstitution/dilution and transfer of drugs/diluents. 	Same

Table: Side-by-side comparison of intended use and technology & design

Characteristic compared	Predicate Device (K201415) Vial2Bag Advanced™ *20 mm Admixture Device*	Subject Device (K252987) ADRx™ *Admixture Device*	Comment/ Discussion
Vial closure size	20 mm	**13 mm** and 20 mm	Different See **Comment #2**
Bag spike design	Dual-channel bag spike		Same
	ISO 8536-4:2019 compliant bag spike		Same
Number of access points	Device has three (3) access points: 1. I.V. bag piercing spike, 2. Injection port/medication access port, 3. Spiking port/administration port		Same
Biocompatibility of fluid path materials	Materials that were tested in accordance with the ISO 10993-1 standard and/or USP VI requirements and were determined suitable for the *Indications for Use* of the product (respective devices)		Same
	Particulate testing was conducted		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
Single use or reusable	Single use only		Same
Labeling specs	Met the requirements specified in 21 CFR 801		Same

Submitter's Comments

Comment #1 on Indications for Use

Both the Subject device (**ADRx™ *SingleDose* & ADRx™ *UniqDose***) and the Predicate device (**Vial2Bag Advanced™**) are intended to function as connectors between an I.V. bag and an external I.V. administration set, enabling the admixture of drugs into infusion solutions. Each device establishes a sterile fluid pathway between vials and I.V. bags, and vice versa to support safe drug/fluid transfer. Both devices are compatible with standard I.V. bags and administration sets as specified in **ISO 8536-4:2019**, and operates on the same manual principles of use

Comment #2 on Vial Sizes

All differences, including the vial adaptor dimensional variation for 13 mm and 20 mm vial closures, were thoroughly evaluated through verification testing conducted on twice-EO-sterilized and aged devices and their protective packaging, over the full labeled shelf life. These tests included mechanical performance (e.g., attachment/detachment forces, leakage), functional transfer efficiency, and packaging integrity, performed in accordance with FDA-recognized standards (e.g., ISO 8536-4:2019, USP <788>, and ASTM F1980). Results confirmed that these differences do **not** introduce new or different questions regarding safety and effectiveness

VII. Performance Data Supporting Substantial Equivalence

A. Performance Testing

The Subject device was evaluated to be in conformance with the following ISO and FDA recognized standards, and FDA guidance document:

- **ISO 8362-2:2024**, *Injection containers and accessories — Part 2: Closures for injection vials*
- **ISO 8536-2:2023**, *Infusion equipment for medical use — Part 2: Closures for infusion bottles*
- **ISO 8536-4:2019**, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- **ISO 8871-5:2016**, *Elastomeric parts for parenterals and for devices for pharmaceutical use Part 5: Functional requirements and testing*
- **ISO 15747:2018**, *Plastic containers for intravenous injections*
- **ISO 22413:2021**, *Transfer sets for pharmaceutical preparations — Requirements and test methods*
- **ISO 80369-7:2021,** *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*
- ***Intravascular-Administration-Sets-Premarket-Notification-Submissions-[510(k)]---Guidance-for-Industry-and-FDA-Staff***

The following performance testing executed on twice-EO sterilized, aged devices confirmed operational integrity:

Mechanical Tests

- 1m Drop Durability
- Attachment Force of Vial Adapter to Vial
- Detachment Force of Vial Adapter from Vial
- IV Port Tensile Strength
- Bag Spike Penetration Force Test (functional) – per ISO 22413:2021, Section 6.6, Annex A.7
- IV Spike to IV Port Attachment Force
- IV Spike from IV Port Detachment Force
- IV Spike Protector Detachment Force
- Protective Cap Tests (bag spike, spiking port & vial adaptor) (functional)– ISO 8536-4:2019 Section 7.13
- Residual Volume
- Vial Adaptor Spike Penetration Force Test (vial adaptor to vial closure) (functional) – per ISO 8536-2:2023 Section 7.2, Annex B
- Vial Adaptor Tensile Detachment Force
- Tensile Strength Test (functional)– per ISO 8536-4:2019, paragraph 7.3 and Annex A.4
- Vial Adaptor Torque Test and Vial Adaptor Torsional Breakage
- Vial Adaptor Wings Breakage
- Vial Attachment Force
- Vial Detachment Force
- Visual Inspection for Product Damage
- Visual Inspection of Device
- Coring
- Fragmentation
- Mass Transfer
- Luer Lock Connection Test – per ISO 80369-7:2021, Clause 6.1.3, 6.2, 6.3, 6.4, 6.5 and 6.6

Leakage Tests

- Airtightness & Fluid Leakage Integrity Test (including vial adaptor–vial stopper/closure interface) (functional) – per ISO 8536-4:2019, para. 7.2 & Annex A.3
- Leakage after Removal of Twist Off
- Leakage at Vial Adaptor and Stopper/Closure Interface
- Leakage Test (Device)
- Leakage Test (IV spike to IV port)
- Leakage Testing, Internal Diameter of Upper Skirt

Functional Tests

- Dose Concentration (K240940) and Dose Concentration of Delivery Profile
- Uniform Mixing and Transfer Performance (functional) – in-house test method
- Short Circuit Test
- Transfer of Vial Contents to Administration Set
- Transfer of Vial Contents to Bag

B. Biocompatibility

In accordance with ISO 10993-1:2018, the Subject device just like the below listed existing cleared devices, is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were performed on relevant devices cleared under K151650, K241988, K223674/S001 and the Subject device:

- **Cytotoxicity** to ISO 10993-5:2009
- **Sensitization** to ISO 10993-10:2010 & ISO 10993-10:2021
- **Intracutaneous Reactivity** to ISO 10993-23:2021
- **Acute Systemic Toxicity** to ISO 10993-11:2017
- **14-day Subacute/ Subchronic Acute Systemic Toxicity** to ISO 10993-11:2017
- **In-vitro Hemolysis Assessment** to ISO 10993-4:2017 & ASTM F756-17
- **Material Mediated Pyrogenicity** to ISO 10993-11:2017 & USP <151>
- **Chemical Requirements** to ISO 15747:2018, Annex B
- **Particulate matter testing** was conducted on the Subject device, in accordance with ISO 8536-4: 2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed* and USP <788> *Particulate Matter in Injections*
- **EO and ECH residues testing** were conducted on the Subject device, in accordance with ISO 10993-7:2008/Amd.1:2019 for neonate patient population

C. Sterility, Shipping, and Shelf-Life

The Subject device complies with sterilization requirements of ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices* and the following testing/ evaluations conducted on the Subject device:

- **Simulated shipping testing** per ASTM D 4169-16*, Standard Practice for Performance Testing of Shipping Containers and Systems* conducted under K252987
- **Package integrity tests** per ASTM F1980-21, *Standard guide for accelerated aging of sterile barrier systems for medical devices and* Sterile Barrier Packaging Testing performed on the proposed device: Seal strength – ASTM F88/F88M-21, *Standard test method for seal strength of flexible barrier materials*; Dye Penetration – ASTM F1929-23, *Standard test method for detecting seal leaks in porous medical device packaging by dye penetratio*n; EN 868-5:2009, *Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods*
- **Pyrogen tests** per ANSI/AAMI ST72/2019, *Bacterial endotoxins – Test methods, routing monitoring,* and *alternatives to batch testing,* USP 40 <151>, *Pyrogen test (USP rabbit test),* USP-NF <161>, *Medical Devices-Bacterial Endotoxin and Pyrogen Tests,* USP-NF <85>, *Bacterial Endotoxins Test* and testing will be conducted on every lot
- **Shelf-life** of 3 years has been validated using the FDA recognized standard, ASTM 1980-21, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

VIII. Clinical Tests

Not applicable

IX. Conclusion

Based on the comparative analysis and verification testing performed to FDA-recognized standards, **ADRx™ *Admixture Device*** does not raise new questions of safety or effectiveness. Therefore it is substantially equivalent to the Predicate, **Vial2Bag Advanced™ *20 mm Admixture Device*** (**K201415**) in intended use and technological characteristics, per US FDA 510(k) requirements