April 24, 2026

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

Re: K250234
Trade/Device Name: SMARTeZ™ Elastomeric Infusion Pump (RS series)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MEB
Dated: March 25, 2026
Received: March 25, 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
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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)*
K250234

Device Name
SMARTeZ™ Elastomeric Infusion Pump (RS series)

Indications for Use *(Describe)*
The SMARTeZ Pump (Long infusion time article) is intended for continuous infusion of medications for general infusion use, including pain management.
• Routes of administration: intravenous and subcutaneous.
The SMARTeZ Pump (Short infusion time article) is intended for continuous infusion of medications for general infusion use, including antibiotic delivery.
• Route of administration: intravenous.
The SMARTeZ Pump (Chemotherapy article) is intended for continuous infusion of chemotherapy medications.
• Routes of administration: intravenous and intra-arterial.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K250234 – 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: April 15, 2026
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Traditional

II. Subject Device

510(k) Number:	K250234
Trade/ Device Name:	SMARTeZ™ *Elastomeric Infusion Pump (RS)*
Common/ Usual Name:	Pump, Infusion, Elastomeric
Regulation Number:	21 CFR 880.5725
Regulation Name:	Infusion Pump
Regulatory Class:	Class: II
Product Code:	MEB

III. Predicate

510(k) Number:	K151650
Trade/ Device Name:	SMARTeZ™ *Elastomeric Infusion Pump*
Common/ Usual Name:	Pump, Infusion, Elastomeric
Regulation Number:	21 CFR 880.5725
Regulation Name:	Infusion Pump
Regulatory Class:	Class: II
Product Code:	MEB

IV. Purpose of Submission and Device Description

The SMARTeZ™ *Elastomeric Infusion Pump (RS)*, SMARTeZ™ *RS*, or *RS Pump*, is a sterile, single-use, non-electronic elastomeric infusion pump designed for continuous drug delivery. It utilizes a self-pressuring elastomeric reservoir as its energy source, which drives the fluid through an integrated administration line and flow restrictor to the patient connection. The device is intended exclusively for infusion therapy and not for fluid storage.

The Submission introduces a new series within the SMARTeZ™ product family (previously cleared under K151650 and K242152), expanding the portfolio with enhanced structural features and consistent performance characteristics.

All SMARTeZ™ infusion pumps operate on the same physical principle: flow control is achieved via a restriction in the inner diameter of the tubing, while the elastomeric reservoir provides the energy for fluid delivery. When filled, the reservoir membrane stretches, and its elastic recoil drives the fluid through the tubing and flow restrictor to the patient.

These differences do not introduce new questions of safety or effectiveness and are supported by analytical and functional testing, as detailed in **Section VI**.

V. *Indications for Use* Statement

The SMARTeZ *Pump* (Long infusion time article) is intended for continuous infusion of medications for general infusion use, including pain management.

- Routes of administration: intravenous and subcutaneous.

The SMARTeZ *Pump* (Short infusion time article) is intended for continuous infusion of medications for general infusion use, including antibiotic delivery.

- Route of administration: intravenous.

The SMARTeZ *Pump* (Chemotherapy article) is intended for continuous infusion of chemotherapy medications.

- Routes of administration: intravenous and intra-arterial.

VI. Comparison of *Intended Use & Technological Characteristics*

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

Intended Use comparison

1) *Indications for use* statement
2) Primary product code and regulation number
3) Intended user population/ intended use environment
4) Intended drug type
5) Types of infusion therapies
6) Routes of infusion
7) Medical delivery method
8) Prescription use or over-the-counter use

Technological Characteristics comparison

Equivalencies – *Technology & Design*

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

1) Principles of operation
2) Energy source
3) Particle filter pore size
4) Performance specifications
5) Sterile barrier packaging
6) Sterilization process
7) Shelf-life
8) Single use or reusable
9) Labeling specifications

In addition to standard risk management, a Safety Assurance Case was included in this Submission to support the safety and performance of the SMARTeZ™ *RS*, in alignment with US FDA's *Infusion Pump Improvement Initiative*. An overview table summarizing the comparison of the key characteristics between the Subject and the Predicate device is provided hereunder:

Comparison of intended use characteristics and the technological characteristics

Characteristic compared	**Predicate Device** (K151650) SMARTeZ™ *Elastomeric Infusion Pump*	**Subject Device** (K250234) SMARTeZ™ *Elastomeric Infusion Pump (RS)*	**Comment/ Discussion**
Intended use and *Indications for Use* statement	The SMARTeZ Pump (Long infusion time article) is intended for continuous infusion of medications for general infusion use, including pain management. • Routes of administration: intravenous and subcutaneous. The SMARTeZ Pump (Short infusion time article) is intended for continuous infusion of medications for general infusion use, including antibiotic delivery. • Route of administration: intravenous. The SMARTeZ Pump (Chemotherapy article) is intended for continuous infusion of chemotherapy medications. • Routes of administration: intravenous and intra-arterial.		Same
Primary product code and regulation number	MEB 21 CFR 880.5725		Same
Intended user population/ intended use environment	Adequately trained health care professionals/ clinical setting		Same
Intended drug type	Parenteral drugs		Same
Types of infusion therapies	4 types: General infusion including chemotherapy, analgesia and antibiotic therapy		Same
Routes of infusion	3 types: IV, IA, subcutaneous		Same
Medical delivery method	Continuous fixed flow rate		Same
Prescription use or over-the-counter use	℞ only		Same
Principles of operation	Hagen-Poiseuille law		Same
Energy source	Constriction of elastomeric membrane of fluid reservoir		Same

Comparison of intended use characteristics and the technological characteristics

Characteristic compared		**Predicate Device** (K151650) SMARTeZ™ *Elastomeric Infusion Pump*	**Subject Device** (K250234) SMARTeZ™ *Elastomeric Infusion Pump (RS)*	Comment/ Discussion
Device construction	Device components	• Fluid reservoir, administration tube, flow restrictor, distal connector with safety closing cap, made of plastics and elastomer • Fill port: Check valve, female Luer lock • Fluid reservoir: Elastomeric silicone rubber membrane • Administration tubing: Included in the device, together with air and particulate filter. • Kink-resistant PVC infusion line not made with *DEHP (Di(2-ethylhexyl)phthalate)*. • Flow restrictor: Plastic micro bore tube, and plastic capillary tube		Same
	Outer shell	**Soft** outer shell	**Hard** outer shell	Different, see **Comment #1**
	Inline Fill Port & **TPU Tube** (clamp portion of tube)	**Do not not exist**	**Are present**	Different, see **Comment #2**
Particle filter pore size		1.2 µm		Same
Performance specifications		ISO 28620:2020, Medical devices — Non-electrically driven portable infusion devices		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 specifications		Met the requirements specified in 21 CFR 801		Same

Submitter's Comments

Comment #1

Subject device incorporates a hard outer shell compared with Predicate device which incorporates a soft outer shell. This difference between the Subject device and Predicate device did not raise different questions of safety and effectiveness as analytical and functional testing have also been conducted and the functional performance data are summarized in subsection **VII.A – Functional Performance**. The analytical aspects are presented in **VII.B – Biocompatibility**

Comment #2

Subject device incorporates an *Inline Valve Fill Port* and a *TPU Tube* and as compared with Predicate device, these subcomponents do not exist. This difference between the Subject device and Predicate device did not raise different questions of safety and effectiveness as analytical and functional testing have also been conducted. The functional performance data are summarized in subsection **VII.A – Functional Performance** and the biocompatibility testing and chemical characterization data are summarized in subsection **VII.B – Biocompatibility**

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 product code-applicable FDA's 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 28620:2020** – *Medical devices — Non-electrically driven portable infusion devices*
- ***Infusion Pumps Total Product Life Cycle – Guidance for Industry and FDA Staff (2014)***

Comprehensive bench performance verification and validation testing was performed on the Subject device and the Predicate device (K151650) to demonstrate substantial equivalence and compliance with applicable guidance:

- **Leak-proof tests** under these conditions – **i)** after resistance to pressure test (on Subject device), **ii)** after accelerated ageing and resistance to pressure test (on Subject device), **iii)** after drop test (on Subject device), **iv)** after resistance to traction test (on Subject device), **v)** after drop test and storage for 12 hours (on Subject device), **vi)** after refrigeration; to ISO 28620:2020, subclause 6.3, 6.4, 6.5 & 6.6 (under K151650)
- **Flow rate tests** under these conditions – **i)** under nominal condition, mean flow rate within ± 15% of the nominal flow rate and ≥ 80% of nominal flow rate delivered at an instantaneous flow rate within ± 50% of the nominal flow rate (on Subject device), **ii)** after accelerated ageing, mean flow rate within ± 15% of the nominal flow rate and ≥ 80% of nominal flow rate delivered at an instantaneous flow rate within ± 50% of the nominal flow rate (on Subject device), **iii)** delivery of normal saline 0.9% at 31º C with pump positioned at 40 cm below the catheter site, mean flow rate within ± 15% of the nominal flow rate and ≥ 80% of nominal flow rate delivered at an instantaneous flow rate within ± 50% of the nominal flow rate (on Subject device), **iv)** after resistance to pressure test, mean flow rate within ± 15% of the nominal flow rate and ≥ 80% of nominal flow rate delivered at an instantaneous flow rate within ± 50% of the nominal flow rate (on Subject device), **v)** after resistance to traction test, mean flow rate within ± 15% of the nominal flow rate and ≥ 80% of nominal flow rate delivered at an instantaneous flow rate within ± 50% of the nominal flow rate (on Subject device), **vi)** after accelerated ageing and resistance to pressure test, mean flow rate within ± 15% of the nominal flow rate and ≥ 80% of nominal flow rate delivered at an instantaneous flow rate within ± 50% of the nominal flow rate (on Subject device), **vii)** after refrigeration, under non-ambient pressure (simulating influences of routes of administration); to ISO 28620:2020, subclause 6.2 & 6.6 (under K151650)
- **Retrograde flow of infusate tests** (under K151650)
- **Luer lock connection tests** on the new *Luer* lock connectors – **i)** positive pressure fluid leakage test, **ii)** sub-atmospheric pressure air leakage test, **iii)** stress cracking test, **iv)** resistance to separation from axial load test, **v)** resistance to separation from unscrewing test, **vi)** resistance to overriding test, to ISO 80369-7:2021 performed on the Subject device

B. Biocompatibility

In accordance with ISO 10993-1:2018, the Subject device, like the existing SMARTeZ™ *Pump*, is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were conducted on the Subject device:

- **Cytotoxicity** to ISO 10993-5:2009
- **Sensitization** to ISO 10993-10:2010
- **Intracutaneous Reactivity** to ISO 10993-23:2021
- **Acute Systemic Toxicity** to ISO 10993-11:2017
- **Subacute/Subchronic Systemic Toxicity** to ISO 10993-11:2017
- **In-vitro Hemolysis** to ISO 10993-4:2017
- **Material Mediated Pyrogenicity** to ISO 10993-11:2017
- **Chemical Characterization and Toxicological Risk Assessment** to ISO 10993-18:2020 & ISO 10993-17:2002
- **Particulate Matter** to 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*

C. Sterility, Shipping, and Shelf-Life

The Subject SMARTeZ™ *RS*, like the existing SMARTeZ™ *Pump*, 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
- **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* under K151650

VIII. Clinical Tests

Not applicable

IX. Conclusion

Based on the comparative analysis and performance data, the **SMARTeZ™ *Elastomeric Infusion Pump (RS)* submitted under K250234** does not raise new questions of safety or effectiveness. Therefore it is substantially equivalent to the Predicate device, **SMARTeZ™ *Elastomeric Infusion Pump*** (K151650), per US FDA 510(k) requirements