October 7, 2024

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

Re: K242152
Trade/Device Name: SMARTeZ™ Elastomeric Infusion Pump (498111, 498121, 498131, 498141)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MEB
Dated: September 9, 2024
Received: September 9, 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.

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
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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.

Submission Number *(if known)*

K242152

Device Name

SMARTeZ™ Elastomeric Infusion Pump (498111, 498121, 498131, 498141)

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.

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K242152 – 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: September 9, 2024
Content and Format: Prepared in accordance with 21 CFR 807.92
Type of Submission: Special

II. Subject Device

510(k) Number:	K242152
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

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* (SMARTeZ™ *Pump*) is a sterile, single-use, mechanical (non-electric, non-electronic) infusion pump that consists of an elastomeric fluid reservoir as an energy source and an administration line. The constriction of the elastomeric fluid reservoir drives the fluid through the administration tubing and eventually through a flow restrictor, into the patient connection.

The SMARTeZ™ *Pump* is intended to administer infusion therapies only, and not for fluid storage.

This Special 510(k) Submission is to inform FDA of the addition to the thirty-nine (39) existing SMARTeZ™ *Pump* offerings, four (4) new models of different nominal volumes, flow rates and time: **498111**: 100 ml, 0.5 ml/h, 200 h; **498121**: 100 ml, 1 ml/h, 100 h: **498131**: 50 ml, 0.5 ml/h, 100 h; **498141**: 50 ml, 1 ml/h, 50 h, with KVO (Keep Vein Open) infusion pump labeling.

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* statements
2) Primary product code and regulation number
3) Intended user population/ intended use environment
4) Intended drug type
5) Type of infusion
6) Routes of the infusion
7) Medical delivery method
8) Single use or reusable
9) Prescription use or over-the-counter use
10) Labeling specifications

Technological characteristics comparison

Equivalencies – Technology & Design

The Subject device and the Predicate device share the following design characteristics, and from the evaluation in the comparison table, there was no substantial difference from the Predicate device identified, that would raise a safety or performance issue/ concern:

1) Principles of operation
2) Energy source
3) Device construction (major components, construction of materials, fill port, fluid reservoir, administration tubing, outer shell, flow restrictor)
4) Performance specification
5) Sterile barrier packaging
6) Sterilization process
7) Shelf-life

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

Characteristic compared	**Predicate Device** (K151650) SMARTeZ™ *Elastomeric Infusion Pump*	**Subject Device** (K242152) SMARTeZ™ *Elastomeric Infusion Pump*	**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."	"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	MEB 21 CFR 880.5725	Same
Intended user population/ intended use environment	Adequately trained health care professionals/ clinical setting	Adequately trained health care professionals/ clinical setting	Same
Intended drug type	Parenteral drugs	Parenteral drugs	Same

Characteristic compared		**Predicate Device** (K151650) SMARTeZ™ *Elastomeric Infusion Pump*	**Subject Device** (K242152) SMARTeZ™ *Elastomeric Infusion Pump*	Comment/ Discussion
Type of infusion		General infusion	General infusion	Same
Routes of infusion		Through clinically accepted routes	Through clinically accepted routes	Same
Medical delivery method		Continuous fixed flow rate	Continuous fixed flow rate	Same
Single use or reusable		Single use only	Single use only	Same
Prescription use or over-the-counter use		℞ only	℞ only	Same
Labeling specifications		Meets the requirements specified in 21 CFR 801	Meets the requirements specified in 21 CFR 801	Same
Principles of operation		Hagen-Poiseuille law	Hagen-Poiseuille law	Same
Energy source		Constriction of elastomeric membrane of fluid reservoir	Constriction of elastomeric membrane of fluid reservoir	Same
Device construction	Major components	Fluid reservoir, administration tube, flow restrictor, distal connector	Fluid reservoir, administration tube, flow restrictor, distal connector	Same
	Construction of materials	Plastics and elastomer	Same plastics and elastomer	Same
	Fill port	Check valve, female Luer lock	Check valve, female Luer lock	Same
	Fluid reservoir	Multi-layer elastomer membrane	Multi-layer elastomer membrane	Same
	Administration tubing	Included in the device, together with air and particulate filter	Included in the device, together with air and particulate filter	Same
	Outer shell	Soft flexible outer shell	Soft flexible outer shell	Same

Characteristic compared		**Predicate Device** (K151650) SMARTeZ™ *Elastomeric Infusion Pump*	**Subject Device** (K242152) SMARTeZ™ *Elastomeric Infusion Pump*	**Comment/ Discussion**
	Flow restrictor	Plastic micro bore tube and plastic capillary tube	Plastic micro bore tube and plastic capillary tube	Same
Performance specifications		ISO 28620:2020, Medical devices – Non-electrically driven portable infusion devices	ISO 28620:2020, Medical devices – Non-electrically driven portable infusion devices	Same
Detachable/bonded administration tube		Administrated tube bonded to pump	Detachable administration tube, packed in the same unit packaging as the pump	Different, see **Comment #1**
Sterile barrier packaging		Medical grade paper and medical plastic film, heat sealed	Medical grade paper and medical plastic film, heat sealed	Same
Sterilization process		Ethylene Oxide (EO), SAL 10^{-6}	Ethylene Oxide (EO), SAL 10^{-6}	Same
Shelf-life validation		3 years (36 months)	3 years (36 months)	Same

Discussion of difference in technological characteristics

Comment #1

The administration tube, which is presented in the same unit package, is to be attached by the health care professional, The Subject device with the change was subjected to testing to ISO 28620:2020 - with the administration tube portion attached to the pump portion - and the new Luer connectors, to ISO 80369-7:2021. Testing confirmed the device was safe and effective. The difference between the Subject device and Predicate (existing) device did not raise different questions of safety and effectiveness. Its testing summary is provided in VII.A, hereunder.

VII. Performance Data Supporting Substantial Equivalence

A. Functional Performance

The Subject device in this Summary was evaluated to be in conformance with the following ISO standards document:

- ISO 28620:2020, *Medical devices — Non-electrically driven portable infusion devices*
- ISO 80369-7 Second edition 2021-05 — *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*

Bench performance verifications and validations performed on the Subject device (pump and administration tubing connected) and referred-to existing devices (K151650):

- Flow rate test under these conditions – nominal (on Subject device), various ambient temperature, various solution viscosity, after resistance to pressure (on Subject device), after resistance to traction test (on Subject device), after refrigeration, under non-ambient pressure (simulating influences of routes of administration); to ISO 28620:2020, subclause 6.2 & 6.6, all under K151650 and where indicated, on the Subject device as well
- Leak-proof test under these conditions – resistance to pressure (on Subject device), after drop test, after resistance to traction test (on Subject device), after refrigeration; to ISO 28620:2020, subclause 6.3, 6.4, 6.5 & 6.6, All under K151650 and where indicated, on the Subject device as well
- Retrograde flow of infusate test, under K151650
- Luer lock connection tests on the new Luer lock connectors – 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 test, to ISO 80369-7:2021 performed on the Subject device

B. Biocompatibility

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

- Cytotoxicity to ISO 10993-5 under K151650
- Sensitization to ISO 10993-10 under K151650
- Intracutaneous Reactivity to ISO 10993-10 under K151650
- Acute Systemic Toxicity to ISO 10993-11 under K151650
- In-vitro Hemolysis Assessment to ISO 10993-4 under K151650
- Chemical Characterization and Toxicological Risk Assessment to ISO 10993-18 and ISO 10993-17, under K151650

C. Sterility, Shipping, and Shelf-Life

The Subject device, 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 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*
- 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 1980-21,

  Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

VIII. Clinical Tests

Not applicable.

IX. Conclusion

The difference between the Predicate and the Subject device does not raise any new or different questions of safety or effectiveness. The Subject device – SMARTeZ™ *Elastomeric Infusion Pump* (submitted under K242152) – is substantially equivalent to the Predicate device, and existing device, the SMARTeZ™ *Elastomeric Infusion Pump* (cleared under K151650) – with respect to its indications for use, principles of operation and technological characteristics.