March 24, 2021

Epic Medical Pte. Ltd.
% Roshana Ahmed
Sr. Consultant, Regulatory Affairs Medical Devices
Quaras, LLC
25 Independence Blvd.
Warren, New Jersey 07059

Re: K201626
Trade/Device Name: Safety Subcutaneous Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: February 17, 2021
Received: February 19, 2021

Dear Roshana Ahmed:

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,

for Payal Patel
Acting 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)*
K201626

Device Name
Safety Subcutaneous Infusion Set

Indications for Use *(Describe)*
The Safety Subcutaneous Infusion Set is indicated for subcutaneous infusion of medication administered by an external infusion pump or syringe.

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."

K201626 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
Date Prepared: February 16, 2021

II. Device

Device Proprietary Name:	Safety Subcutaneous Infusion Set
Common or Usual Name:	Subcutaneous Administration Set
Classification Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Product Code:	FPA
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- SUB-Q Subcutaneous Tissue Infusion Set, K140131, EMED Technologies Corporation

IV. Device Description

The Safety Subcutaneous Infusion Set is an intravascular administration set used to administer medication subcutaneously. The device consists of subcutaneous stainless-steel needle mounted to a wing stabilizer at 90° at the distal end of the infusion set. The subject device has closing type wings to allow the user to insert the needle into the subcutaneous tissue and also secure the needles on the infusion site. A female luer connector is provided at the proximal end to allow connection to external devices.

Each set consists of the administration set and standard medical dressing to secure the needles on the infusion site. The subject device is provided in various needle gauges and lengths. Each needle is equipped with an open end slide clamp on the tubing to facilitate stop flow when required during priming of individual needles.

V. Indications for Use

The Safety Subcutaneous Infusion Set is indicated for subcutaneous infusion of medication administered by an external infusion pump or syringe.

VI. Comparison of Technological Characteristics

The Safety Subcutaneous Infusion Set has the same intended use as the predicate device (K140131). The Safety Subcutaneous Infusion Set has the same general design construction, proximal interface, number of lumens, range of needle gauge and length, tubing length, number of needles, needle safety feature, clamp type, wing type, and sterilization method/level as the predicate device (K140131).

The subject device differs from the predicate device with respect to needle protective cap design, materials of construction and packaging materials.

The table below compares the subject and predicate devices.

Technological comparison

	Safety Subcutaneous Infusion Set (K201626)	**SUB-Q Subcutaneous Tissue Infusion Set (K140131)**	**Comparison**
Indication for Use	The Safety Subcutaneous Infusion Set is indicated for subcutaneous infusion of medication administered by an external infusion pump or syringe.	SUB-Q Subcutaneous Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.	Same as predicate
Proximal interface	Female Luer Lock	Female Luer Lock	Same as predicate
Tubing length	40 cm	5 cm ~ 91.4 cm	Similar to predicate
Needle gauge	24, 26, and 27	24 and 27	Similar to predicate
Needle lengths	6mm, 9mm, 12mm	6mm, 9mm, 12mm, 14mm and 16mm	Same as predicate
Number of needles	1 - 4	1 - 4 (up to 8 with Y connector)	Same as predicate
Needle lubricant	Polydimethylsiloxane (PDMS)	Polydimethylsiloxane (PDMS)	Same as predicate
Wing type	Closed, Needle protecting	Standard and Closed	Same as predicate
Needle protective cap	Sliding	Tubular sheath	Different

	Safety Subcutaneous Infusion Set (K201626)	**SUB-Q Subcutaneous Tissue Infusion Set (K140131)**	**Comparison**
Needle safety feature	Needle inaccessible to user before engaging. Sharp protection feature compliant to ISO 23908:2011.	Needle inaccessible to user before engaging. Sharp protection feature compliant to ISO 23908:2011.	Same as predicate
Sterilization	ETO, SAL of 10^{-6}	ETO, SAL of 10^{-6}	Same as predicate
Priming volume	24-gauge needle: 0.4 ~ 1.4 27-gauge needle: 0.1 ~ 0.4	24-gauge needle: 0.16 ~ 0.8 27-gauge needle: 0.12 ~ 0.8	Similar to predicate
Transparent dressing	Off-the-shelf dressing purchased from: 3M Healthcare	Off-the-shelf dressing purchased from: 3M Healthcare	Same as predicate
Component materials	Luer lock: ABS Luer cap: LDPE Tubing: PVC Wings: Polypropylene and Thermoplastic elastomer (locking) Protective cap: Polycarbonate Needles: Stainless steel Slide clamp: Polyethylene Bonding agent: Cyanoacrylate	Luer lock: PVC Luer cap: Polypropylene Tubing: PVC Wings: PVC (std) and Polypropylene (locking) Protective cap: Polypropylene Needles: Stainless steel Slide clamp: ABS Bonding agent: Cyanoacrylate	Different

Discussion

The Safety Subcutaneous Infusion Set has the same intended use as the predicate device and both the subject and predicate device share the same design, proximal interface, needle lengths, number of needles and needle safety feature, and wing type. The subject device tubing length and needle gauges and fall within the range of tubing length and needle gauges for the predicate device.

The subject device differs from the predicate device with respect to protective cap design (sliding cap design vs. tubular sheath design), priming volume (slight difference in priming volume), and materials of construction for a subset of components. These technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness and are addressed by the performance and biological safety testing identified below.

VII. Performance Data

The following non-clinical data were provided in support of the substantial equivalence determination:

- biocompatibility studies per ISO 10993-1:2018
- particulate matter per USP <788>
- sterilization validation
- ethylene oxide residuals per ISO 10993-7:2008
- shelf life per ASTM F1980-16
- sharps protection per ISO 23908:2011
- tensile strength and water tightness per ISO 8536-8:2015
- luer lock connection test per ISO 80369-7

VIII. Conclusion

The information provided above supports that the Safety Subcutaneous Infusion Set is as safe and effective as the predicate device. Although there are minor technological differences between the subject and predicate devices, these difference do not raise different questions of safety and effectiveness. Therefore, it is concluded that the Safety Subcutaneous Infusion Set is substantially equivalent to the predicate device.