November 3, 2023

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

Re: K230343
Trade/Device Name: ProSeal™ Closed System Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: October 3, 2023
Received: October 3, 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 (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.

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

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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OHT3: Office of Gastrorenal, ObGyn,
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230343

Device Name
ProSeal™ Closed System Administration Set

Indications for Use *(Describe)*
The Administration Sets are intravenous administration sets intended for delivery of medications and fluids from a container into a patient's vascular system.

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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K230343 - 510(k) Summary

I. Submitter

Epic Medical Pte. Ltd.
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Phone: +65 9635 2618 / +66 81 761 5292

Contact Person: Mr. Freddie LEE, Chief Executive Officer/ Managing Director
Date Prepared: November 3, 2023

II. Subject Device

510(k) Number:	K230343
Proprietary/Trade Name:	ProSeal™ *Closed System Administration Set*
Common /Usual Name:	I.V. Administration Set
Regulation Name:	Set, Administration, Intravascular
Product Code:	FPA
Regulation Number:	21 CFR 880.5440
Device Class:	Class: II

III. Predicate Device

510(k) Number:	K151151
Proprietary/Trade Name:	U & U *Intravascular Administration Set*
Common /Usual Name:	I.V. Administration Set
Regulation Name:	Set, Administration, Intravascular
Product Code:	FPA
Regulation Number:	21 CFR 880.5440
Device Class:	Class: II

IV. Device Description

The ProSeal™ *Closed System Administration Set* is a single use-, disposable-, intravenous-administration set used to deliver fluids from a container into a patient's vascular system.

The device comprises an injector, a drip chamber* with a 15-µm particulate filter, a roller clamp, flexible IV tubings*, a luer connector and a priming cap with a 3-µm air filter. ProSeal™ *Closed System Administration Set* may be used in combination with standard IV therapy devices widely used throughout the health care industry, e.g. luer lock adaptor and IV extension sets. ProSeal™ *Closed System Administration Set* is configured to achieve the intended use when used in combination with these aforementioned standard complementary products.

Based on the approved microbial testing in K192075, the ProSeal injector can be accessed/used for up to maximum of 5 times in 7 days.

* Both the drip chamber and the IV tubings are not made with DEHP *(Di (2-ethylhexyl) phthalate (DEHP))*.

V. *Indications for Use* Statement

The *Administration Sets* are intravenous administration sets intended for delivery of medications and fluids from a container into a patient's vascular system.

VI. Comparison of Technological Characteristics

The ProSeal™ *Closed System Administration Sets* have the same indications for use, comparable principle of operation and the same fundamental scientific technology as the Predicate device (§III). Both devices are composed of similar component types, and both meet the performance specifications in the relevant FDA Recognized Consensus Standards and ISO standards. The IV tubings in both IV administration sets are of extruded Polyvinylchloride (PVC) without Di (2-ethylhexyl) phthalate (DEHP) plasticizer.

Successful completion of biocompatibility laboratory analyses and chemical characterization evaluations per ISO 10993-1 confirmed that differences in materials vs. the Predicate device showed these did not adversely impact the biological or chemical safety of the ProSeal™ *Closed System Administration Set*. Additionally, analytical and functional performance evaluations were conducted to further assure that differences did not adversely affect the substantial equivalence of the Subject device.

An overview table summarizing the comparisons between the Subject ProSeal™ Closed System Administration Set and the Predicate U & U *Intravascular Administration Set* is provided in the table that follows.

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

Technological characteristic compared	**Predicate Device** U & U *Intravascular Administration Set* (K151151)	**Subject Device** ProSeal™ *Closed System Administration Set* (K230343)	**Comment/ Discussion**
Indications for Use statement	The U&U *Intravascular Administration Set* is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.	The *Administration Sets* are intravenous administration sets intended for delivery of medications and fluids from a container into a patient's vascular system.	Same
Product code and regulation number	FPA 21 CFR 880.5440	FPA 21 CFR 880.5440	Same
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
Intended drug type	Parenteral drugs	Parenteral drugs	Same
℞/ Prescription use	℞ only	℞ only	Same
Mode of IV fluid therapy delivery	Gravity administration	Gravity administration	Same
Tubing transparency	The IV tubings are transparent and sufficiently clear so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision	The IV tubings are transparent and sufficiently clear so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision	Same

Technological characteristic compared	**Predicate Device** U & U *Intravascular Administration Set* (K151151)	**Subject Device** ProSeal™ *Closed System Administration Set* (K230343)	**Comment/ Discussion**
Composition of device sub-assemblies/ component parts	Bag Spike – present Injector – not applicable (N.A.) IV tubings – present MLL connector – present Drip chamber – present Needleless Y-Site – present Priming cap – N.A.	Bag Spike – not applicable (N.A.) Injector – present IV tubings – present MLL connector – present Drip chamber – present Needleless Y-Site – absent Priming cap – present	Different, see Comment #1
Composition of fluid -path / -contacting materials	Bag Spike – ABS Injector – N.A. IV tubings – PVC (not made with DEHP) MLL connector – ABS Drip chamber – unknown Needleless Y-Site – unknown Priming cap – N.A.	Bag Spike – N.A. Injector – PP, SUS 304 Steel, TPE IV tubings – PVC *(not made with DEHP)* MLL connector – ABS Drip chamber – PVC (*not made with DEHP)*, ABS, polyethylene terephthalate (PET) Needleless Y-Site – N.A. Priming cap – PP, Polytetrafluoroethylene (PTFE)	Different, see Comment #2
Dimensions of IV set	Set overall length: Not known PVC tubing: Inner diameter (ID): Not known Outer diameter (OD): Not known	Set overall length: 210 cm PVC tubing: Inner diameter (ID): 3.0 mm Outer diameter (OD): 4.0 mm	Different, see Comment #2
Drops/ml	Not known	20 gtt/ml	Different, see Comment #2
Priming volume/ residual volume	Not known	11.86 ml	Different, see Comment #2

Technological characteristic compared	**Predicate Device** U & U *Intravascular Administration Set* (K151151)	**Subject Device** ProSeal™ *Closed System Administration Set* (K230343)	**Comment/ Discussion**
Residual volume in needleless Y-site connector	Not known	Not applicable, Subject device does not incorporate a Y-site connector	Different, see Comment #2
Connector type to IV bag spike	Integrated spike	Proximal connector: closed system injector (The injector was 510(k) cleared (K192075).)	Different, see Comment #1
Connector type at distal side of IV admin. set	Distal connector: Male Luer lock tip (ISO 80369-7)	Distal connector: Male Luer lock tip (ISO 80369-7)	Same
Biocompatibility	Acceptable biological risks established by demonstrating that the device meets ISO 10993-1	Acceptable biological risk management and control were established by demonstrating that the Subject device met ISO 10993-1 through providing data of laboratory analyses of the final finished device, and of evaluations of biological endpoints specified for – the *Nature of Body Contact* category - external communicating device, blood path indirect and; *Contact Duration* type - B – Prolonged (>24h to ≤30d)	Same
Particulate contamination	Met contamination index, N≤90 according to ISO 8536-4, *Infusion Equipment for Medical Use, Part 4: Infusion sets for single use, gravity feed, Annex A, A.2 - Test for particulate contamination*	Met contamination index, N≤90 according to ISO 8536-4, *Infusion Equipment for Medical Use, Part 4: Infusion sets for single use, gravity feed, Annex A, A.2 - Test for particulate contamination* and USP <788> *Particulate Matter in Injection*s	Same

Technological characteristic compared	**Predicate Device** U & U *Intravascular Administration Set* (K151151)	**Subject Device** ProSeal™ *Closed System Administration Set* (K230343)	**Comment/ Discussion**
Primary package top web	Not known	Medical grade paper and medical plastic film, heat sealed	Different, see Comment #3
Sterilization method	Ethylene Oxide, EO, SAL 10^{-6}	Ethylene Oxide, EO, SAL 10^{-6}	Same
Shelf life	3 years (36 months)	3 years (36 months)	Same
Reuse or single-use	Single-use only	Single-use only	Same
Labeling specifications	Meets the requirements specified in 21 CFR 801	Meets the requirements specified in 21 CFR 801	Same

Discussion of differences in technological characteristics

Comment #1

Subject device uses a self-sealing perforator (the integrated ProSeal injector) to connect to an IV fluid bag, whereas the Predicate connects to the IV fluid bag with its integrated spike perforator. Subject device includes a priming cap which will be removed after priming.

The evaluation of the difference is one with equivalence. This was because, based on the approved microbial testing in K192075, the ProSeal injector can be accessed/used for up to maximum of 5 times in 7 days, it was found it did not raise any safety or performance issues/ concerns/ new questions.

Comment #2

Even though there was incomplete Predicate device information to perform comparisons for all component parts, the applicant had established equivalence through testing and provided evidence to support the substantial equivalence evaluation - The sterile, single-use, non-pyrogenic ProSeal™ Closed System Administration Set 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
- ISO 8536-4: 2019, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
- ISO 80369-7: 2016, 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)

This is also described in §VII. The evaluation of equivalence found it did not raise any safety or performance issues/ concerns, or raised new questions, as the materials used in the Subject device are found to have met specified requirements in the testing conducted**.**

Comment #3

The difference is evaluated insignificant even though Predicate information was unknown. Both the Subject and the Predicate devices use medical grade sterile barrier systems for their unit packaging primary materials that are suited for the EO sterilization process, the same as the applicant's previously cleared device, ProSeal™ CSTD (K192075).

Moreover, sterile barrier package integrity testing and performance testing on the final finished Subject devices after simulated shipping and distribution per ASTM D4169-22: Standard Practice for Performance Testing of Shipping Containers and Systems were performed and found to have met the specified requirements therein (§VII-C).

VII. Performance Data Supporting Substantial Equivalence

A. Functional performance

The sterile, single-use, non-pyrogenic ProSeal™ *Closed System Administration Set* 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*
- ISO 8536-4: 2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
- ISO 80369-7: 2016, *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)*

B. Biocompatibility

In accordance with ISO 10993-1: 2018, the ProSeal™ *Closed System Administration Set* is classified as: *Externally Communicating Device, Blood Path Indirect, Prolonged Contact* (>24hr to 30d). The following testing were conducted:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- 14-Day Sub Acute Systemic Toxicity
- In-vitro Hemolysis Assessment
- Material Mediated Pyrogenicity

Particulate matter testing was conducted in accordance with ISO 8536-4: 2019, *Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed, Annex A.2* and USP <788> *Particulate Matter in Injections*.

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.*

- Simulated transportation testing per ASTM D4169-22, *Standard Practice for Performance Testing of Shipping Containers and Systems*
- Package Integrity Test
- Sterile Barrier Packaging Testing performed on the proposed device: Seal strength – ASTM F88/ F88M-21

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. Conclusion

The differences between the Predicate and the Subject device do not raise any new or different questions of safety or effectiveness. The ProSeal™ *Closed System Administration Set* is substantially equivalent to the Predicate, U & U *Intravascular Administration Set*, with respect to the indications for use, principles of operation and technological characteristics.