August 7, 2020

Epic Medical Pte. Ltd.
℅ Roshana Ahmed
Senior Director, Regulatory Affairs, Medical Devices
G&L Scientific, Inc.
25 Independence Blvd.
Warren, New Jersey 07059

Re: K192075
Trade/Device Name: ProSeal CSTD
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: July 7, 2020
Received: July 8, 2020

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)*
K192075

Device Name

ProSeal™ Closed System drug Transfer Device (CSTD)

Indications for Use *(Describe)*

The ProSeal™ Closed System drug Transfer Device (CSTD) mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal system also prevents the introduction of microbial contaminations into the drug or fluid path for up to 7 days when used as intended.

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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510(k) Summary

K192075

I. Submitter

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Contact Person: Mr. Freddie Lee, Chief Executive Officer

U.S. Contact

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Phone: 657-248-7361

Date Prepared: August 6, 2020

II. Device

Device Proprietary Name:	ProSeal™ Closed System drug Transfer Device (CSTD)
Common or Usual Name:	Closed System drug Transfer Device (CSTD)
Classification Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Product Code:	ONB
Device Classification	II

III. Predicate Device

BD PhaSeal® Closed System Drug Transfer Device, K123213, Becton Dickinson & Company

IV. Device Description

The ProSeal™ CSTD is a sterile, single-use, closed system drug transfer device for preparation, reconstitution, compounding and administration of antineoplastic and hazardous drugs intended for use in clinical settings by trained healthcare providers and/or pharmacists.

The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding manufacturer's labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information.

The ProSeal™ CSTD consists of three system components and one accessory:

- ProSeal Vial Adaptor (adaptor to the drug vial)
- ProSeal Injector (adaptor to the Luer Lock tip syringe)
- ProSeal Connector (adaptor for the injection site of IV lines)
- ProSeal Assembly Fixture (an accessory that is non-sterile reusable mechanical device to enable the user to consistently and simply attach the ProSeal Vial Adaptor onto the drug vial)

The closed transfer of liquid takes place as follows:

- Sterile air contained inside a flexible chamber integrated into the ProSeal Vial Adaptor provides pressure equalization of the drug vial in a closed system.
- A double membrane septum utilizing self-sealing elastomeric membranes tightly fits together when the system components engage. A cannula perforates the double membrane for the transfer of liquid. When the cannula is retracted, the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system (tested for 10X transfers performed in 7 days), thereby minimizing the individual and environmental exposure to drug vapor, aerosols, and spills, and also minimizing the risk of microbial contamination.

V. Indications for Use

The ProSeal™ Closed System drug Transfer Device (CSTD) mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal system also prevents the introduction of microbial contaminations into the drug or fluid path when used as intended for up to 7 days.

VI. Comparison of Technological Characteristics

The ProSeal™ CSTD and the predicate device share the following characteristics:

- similar system components, including an assembly fixture which enables the user to attach the vial adaptor to the drug vial;
- use of closed system technology;
- use of an integrated pressure equalization chamber;
- same interface between system components;
- use of luer lock connection to fit to syringe and external IV line;
- use of sharps protection features;
- same materials of construction for vial access spike and cannula; and
- same sterilization method for the syringe access and IV line access device components.

The ProSeal™ CSTD and the predicate device are technologically different with respect to the materials of construction for the fluid path and the sterile barrier, as well as the sterilization method for the Vial Access Device component of the system.

The table below compares key technological features between the subject and predicate devices.

Technological comparison

Comparison Element	**Subject Device**	**Predicate Device**	**Comparison**
	ProSeal™ CSTD	**BD PhaSeal® Closed System Drug Transfer Device (K123213)**	
Indications for Use Statement	The ProSeal™ Closed System drug Transfer Device (CSTD) mechanically prohibits environmental contaminants from entering the system and the escape of drug or vapor concentrations from the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. The ProSeal system also prevents the introduction of microbial contaminations into the drug or fluid path for up to 7 days when used as intended.	The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Phaseal system also prevents microbial ingress.	Same
Intended User Population	Trained healthcare providers or pharmacists	Trained healthcare providers or pharmacists	Same

Comparison Element	**Subject Device**	**Predicate Device**	**Comparison**
	ProSeal™ CSTD	**BD PhaSeal® Closed System Drug Transfer Device (K123213)**	
Intended Use Environment	Clinical Setting	Clinical Setting	Same
Intended Drug	Antineoplastic and hazardous drug	Antineoplastic and hazardous drug	Same
Intended Drug Vial Size	ProSeal Vial Adaptor Standard vial with 20 mm and 28mm neck diameter	PhaSeal Protector Standard vial with 13 mm, 20mm, and 28mm neck diameter	Different The subject device is not intended for use with drug vials with a 13 mm neck diameter. This does not raise new questions of safety and effectiveness.
Intended Syringe	ProSeal Injector Male Luer Lock tip	PhaSeal Injector Male Luer Lock tip	Same
Intended Administration Site	ProSeal Connector Female Luer Lock injection site on IV line	PhaSeal Connector Female Luer Lock injection site on IV line	Same
Single Use	Single Use Only	Single Use Only	Same
Rx	Rx Only	Rx Only	Same
System Components	ProSeal Vial Adaptor ProSeal Injector ProSeal Connector ProSeal Assembly Fixture	PhaSeal Protector PhaSeal Injector PhaSeal Connector PhaSeal Assembly Fixture	Same
System Components Interface	Self-Sealing Elastomeric Membrane on all system components.	Self-Sealing Elastomeric Membrane on all system components.	Same
Drug Vial Interface	ProSeal Vial Adaptor Snap lock and elastomeric membrane	PhaSeal Protector Snap lock and elastomeric membrane	Same
Pressure Equalization Chamber	Integrated into ProSeal Vial Adaptor	Integrated into PhaSeal Protector	Same
	Flexible film	Flexible film	Same
	20 mL	20 mL	Same

Comparison Element	Subject Device ProSeal™ CSTD	Predicate Device BD PhaSeal® Closed System Drug Transfer Device (K123213)	Comparison
	50 mL 60 mL	50 mL 60 mL	
Drug Vial Perforator	ProSeal Vial Adaptor Plastic	PhaSeal Protector Stainless Steel or Plastic	Same
Injector Perforator	ProSeal Injector Stainless Steel Cannula	PhaSeal Injector Stainless Steel Cannula	Same
Connection to External Standard Syringe	ProSeal Injector Female Luer Lock	PhaSeal Injector Female Luer Lock	Same
Connection to IV Line	ProSeal Connector Male Luer Lock	PhaSeal Connector Male Luer Lock or Spike Port	Same
Needle Safety Feature	Needle inaccessible to user when engaged and disengaged	Needle inaccessible to user when engaged and disengaged	Same
Sterile Barrier Packaging	Coated medical paper and plastic forming film, heat sealed	Tyvek® and plastic forming film, heat sealed	Similar
Sterilization, Vial Access Device	Gamma, SAL 10^{-6}	EO, SAL 10^{-6}	Different Use of gamma versus EO does not raise any new questions of safety or effectiveness.
Sterilization, Syringe Access	EO, SAL 10^{-6}	EO, SAL 10^{-6}	Same
Sterilization, IV Line Access Device	EO, SAL 10^{-6}	EO, SAL 10^{-6}	Same
Shelf-Life	35 months	3 years	Similar

Discussion

There are slight differences between the subject and predicate devices with respect to the indications for use statement; however, these differences do not alter the overall intended use of the subject device. Both devices are Closed System drug Transfer Devices which protect the drug inside the system from environmental contamination; protect healthcare providers from exposure to drug vapor, aerosols, and spills; protect from microbial ingress into the system; and are intended to be used for drug preparation and administration.

The subject and predicate devices are technologically different with respect to the materials of construction for the fluid path and the sterile barrier, the as well as the sterilization method for the Vial Access Device component of the system. In addition, the subject device is not intended for use with drug vials that have a 13 mm neck diameter. These technological differences do not raise different questions of safety or effectiveness and are addressed by performance data identified below.

VII. Performance Data

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

- Biocompatibility studies per ISO 10993-1:2009
    - Cytotoxicity
    - Sensitization
    - Intracutaneous reactivity
    - Acute systemic toxicity
    - Hemocompatibility
    - Material mediated pyrogenicity
    - Chemical characterization/Toxicological Risk Assessment

Performance testing in accordance with the following standards was conducted on the system components as applicable:

- ISO 11137-1:2006, “Sterilization of Healthcare Products Radiation – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices”
- ISO 11137-2:2013, “Sterilization of Healthcare Products – Part 2 Establishing the Sterilization Dose”
- ISO 11135:2014, “Sterilization of health care product – Ethylene Oxide – Requirement, validation and routine control of a sterilization process for medical devices”
- AAMI TIR28:2016, “Product Adoption and process equivalence for ethylene oxide sterilization”
- USP <85>, Bacterial Endotoxin test
- ASTM F1980-16, “Standard guide for accelerated aging of sterile barrier systems for medical devices”

- ISO 8536-2:2010, “Infusion Equipment for medical use – Part 2: Closures for infusion bottles”
- ISO 7864:2016, “Sterile hypodermic needles for single use – Requirements and test
- methods”
- USP <788>, “Particulate Matter in Injections”
- ISO 23908:2011, “Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling”
- ISO 80369-7:2016, “Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications”

The following performance tests were conducted to internal specifications:

- volume of pressure equalization
- leak integrity
- vapor containment testing with titanium tetrachloride (visual indicator)
- Fluorescein testing – dry connections
- microbial ingress testing
- Assembly fixture validation

VIII. Conclusion

The information provided above supports that the ProSeal™ CSTD is substantially equivalent to the predicate device. Although minor technological differences with respect to the materials of construction for the fluid path and the sterile barrier, the sterilization method for the Vial Access Device component of the system, and the drug vial sizes exists between the subject and predicate devices, the performance testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the ProSeal™ CSTD is substantially equivalent to the predicate device.