Becton, Dickinson and Company
Samhitha Mohan
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

March 11, 2022

Re: K193190
Trade/Device Name: BD PureHub Disinfecting Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Samhitha Mohan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 9, 2020. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

November 9, 2020

Becton, Dickinson and Company
Samhitha Mohan
Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K193190
Trade/Device Name: BD PureHub™ Disinfecting Cap
Regulatory Class: Unclassified
Product Code: QBP
Dated: October 8, 2020
Received: October 9, 2020

Dear Samhitha Mohan:

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,

Sapana Patel -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193190

Device Name
BD PureHub Disinfecting™ Cap

Indications for Use *(Describe)*
BD PureHub™ Disinfecting Caps are intended to be used as a disinfecting cleaner for swabbable needle-free luer connectors prior to access and to act as a physical barrier between line accesses.

BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one (1) minute after application and act as a physical barrier for up to seven (7) days, if not removed.

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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"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."

K193190 - 510(k) Summary (21 CFR §807.92)

BD PureHub™ Disinfecting Cap

Submitter Information	Submitter Name:	Becton, Dickinson and Company
	Submitter Address:	1 Becton Drive Franklin Lakes NJ 07417
	Contact Person:	Samhitha Mohan Staff Regulatory Affairs Specialist
	Email Address:	Samhitha.Mohan@bd.com
	Phone Number:	(201) 847-5204
	Fax Number:	(201) 847-5307
	Date of Preparation:	November 3, 2020
Subject Device	Trade Name:	BD PureHub™ Disinfecting Cap
	Common Name:	Cap, Device Disinfectant
	Regulation Number:	Unclassified
	Device Class:	Unclassified
	Product Code:	QBP
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	Curos™ Port Protector
	510(k) Reference:	K111992
	Common Name:	Cap, Device Disinfectant
	Regulation Number:	Unclassified
	Regulatory Class:	Unclassified
	Product Code:	QBP
	Classification Panel:	General Hospital
Device Description	BD PureHub™ Disinfecting Cap is a sterile, single use disinfectant cap designed for needle-free Luer connectors. It has high-density polyethylene housing and polyester urethane sponge saturated with 70% Isopropyl Alcohol (IPA) solution. PureHub™ disinfects needle-free Luer connectors one minute after application and acts as a physical barrier for up to seven days, if not removed. It is available in two packaging configurations – Bulk Single Unit and IV Pole Strip.	
Indications for Use	BD PureHub™ Disinfecting Caps are intended to be used as a disinfecting cleaner for swabbable needle-free luer connectors prior to access and to act as a physical barrier between line accesses.	

	BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one (1) minute after application and act as a physical barrier for up to seven (7) days, if not removed.
Technological Characteristics	The following table provides a comparison between the subject and predicate device -

Attributes	Subject Device (BD PureHub™ Disinfecting Cap)	Predicate Device (Curos™ Port Protector)	Comparison
Indications for Use	BD PureHub™ Disinfecting Caps are intended to be used as a disinfecting cleaner for swabbable needle-free luer connectors prior to access and to act as a physical barrier between line accesses. BD PureHub™ Disinfecting Cap will disinfect the needle-free luer connector one (1) minute after application and act as a physical barrier for up to seven (7) days, if not removed.	The Curos™ is intended for use on swab-able Luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. Curos™ will disinfect the valve three (3) minutes after application and act a s a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curos™ Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermis, Escherichia coli and Pseudomonas aeruginosa, candida glabrata, Canada albicans and was found to have >4-log reduction. The Curos™ Port Protector may be used in the home or healthcare facility.	With the exception of disinfection time and the microorganisms, the intended use is similar. *In vitro* antimicrobial efficacy testing was performed to support PureHub's disinfection time. The micro-oraganisms tested are identical to Curos™ Port Protector with the exception of the addition of antimicrobial efficacy testing conducted on Acinetobacter baumannii. The subject device does not list the microorganisms tested against in the indications for use.
Condition of Use (Environment)	Same as predicate	Home and health care facility	Identical
Cap Insertion Site	Same as predicate	Needle-free Luer connector	Identical

Device Components		Same as predicate	• Ribbed external cap housing • Sponge with 70% IPA solution • Foil lid	Identical
User Population		Same as predicate	General use	Identical
Operating Principle		Same as predicate	70% IPA solution acts as an antimicrobial agent to disinfect needle-free Luer connector	Identical
Device Materials	Cap Housing	High Density Polyethylene (HDPE)	Unknown	Material differences were assessed as per ISO 10993-1
	Sponge	Polyester Urethane	Unknown	
	Disinfecta -nt Solution	Same as predicate	70% IPA	
	Colorant	Teal green	Translucent green	
Packaging Configurations		Same as predicate	Bulk Single Unit and IV Pole Strip	Identical
Sterilization Method		Same as predicate	Gamma Irradiation	Identical
SAL		Same as predicate	10^{-6}	Identical
Antimicrobial Efficacy		Same as predicate	> 4-log reduction	Identical
Minimum Disinfecting Time		1 minute	3 minutes	Similar; reduced disinfecting time was assessed through antimicrobial efficacy testing.
Target microorganisms for *in vitro* antimicrobial efficacy testing		• Staphylococcus aureus • Staphylococcus epidermidis • Escherichia coli • Pseudomonas aeruginosa • Candida albicans • Candida glabrata • Acinetobacter baumannii	• Staphylococcus aureus • Staphylococcus epidermidis • Escherichia coli • Pseudomonas aeruginosa • Candida albicans • Candida glabrata	Identical except for Acinetobacter baumannii. *In vitro* antimicrobial efficacy testing was performed for all the microorganisms

Shelf Life	3 years	3 years	Identical

Discussion:

The intended use of the subject and predicate device are similar in that both disinfect needle-free Luer connector and act as a physical barrier. However, the disinfection time of PureHub™ (1 minute) is shorter than Curos™ Port Protector (3 minutes) and PureHub™ tests an additional microorganism (Acinetobacter baumannii) compared to Curos™ Port Protector. *In vitro* antimicrobial efficacy testing was performed for all the above mentioned microorganisms to demonstrate that the shorter disinfection time does not raise any new or different questions of safety and effectiveness.

Additionally, since the predicate device materials were unknown, appropriate biocompatibility tests were performed as per ISO 10993-1 to ensure the safe use of PureHub™. The biocompatibility tests performed on the subject device are identified below.

The predicate device has not been subjected to design-related call.

Non-Clinical Testing

BD has performed the following performance tests in accordance with 21 CFR §820.30 to demonstrate that the PureHub™ Disinfecting Cap performs equivalent to the predicate device.

The following tests were performed on the subject device to an internal specification or a Standard:

- *In vitro* Antimicrobial Efficacy
  - *Staphylococcus aureus*
  - *Staphylococcus epidermidis*
  - *Escherichia coli*
  - *Pseudomonas aeruginosa*
  - *Candida albicans*
  - *Candida glabrata*
  - *Acinetobacter baumannii*
- Particulate Matter Ingress USP 788
- 70% IPA Weight and % Isopropyl Alcohol/Water Solution Concentration
- Cap to Connector Interface
  - Device Retention to Luer activated valve (LAV)
  - Material Compatibility of subject device and LAV
    - Air Leakage
    - Weld Retention
- Packaging Integrity
- Tensile Strength on IV Pole Strip
- PureHub™ Connector Air Leak Testing
- Physical Barrier Testing

As per ISO 10993-1:2009, the following biological tests were

	performed: • Cytotoxicity • Sensitization • Irritation or Intracutaneous Activity • Acute Systemic Toxicity • Material Mediated Pyrogenicity • LAL Endotoxin • Hemocompatibility • Subacute/Subchronic Additionally, the following tests were performed – • Chemical Extractable Analysis • 70% IPA Ingress Testing The BD PureHub™ Disinfecting Cap is sterilized by Gamma radiation. The sterilization process was validated in accordance with ISO 11137-2:2013 (VD_{max}^{25}). The subject device met all the predetermined acceptance criteria for the above listed performance tests and demonstrated substantial equivalence to the predicate device.
Clinical Testing	Not applicable.
Summary of Substantial Equivalence	The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The PureHub™ Disinfecting Cap is substantially equivalent to Curos™ Port Protector cleared under K111992 with respect to the indications for use, target population, treatment method and technological characteristics.