July 28, 2021
Becton, Dickinson and Company
Nikita Kumar
Senior Regulatory Affairs Specialist
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K203359
Trade/Device Name: BD Flu+ Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 26, 2021
Received: June 30, 2021

Dear Nikita Kumar:

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 Alan Stevens
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)*
K203359

Device Name
BD™ Flu+ Syringe

Indications for Use *(Describe)*
The BD™ Flu+ Syringe is intended for aspiration and injection of fluids.

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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K203359 510(k) Summary

BD™ Flu+ Syringe

Submitter Information	Submitter Name: Submitter Address: Contact Person: Email Address: Phone Number: Date of Preparation:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 Nikita Abirami Mahendra Kumar Senior Regulatory Affairs Specialist Nikita.Abirami.Mahendra.Kumar@bd.com (201) 847-5641 July 28, 2021
Subject Device	Trade Name: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD™ Flu+ Syringe Piston Syringe 21 CFG 880.5860 Piston Syringe Class II device FMF General Hospital
Predicate Device	Trade Name: 510(k) Reference: Common Name: Regulation Number: Regulation Name: Regulatory Class: Product Code: Classification Panel:	BD™ FLU+ Syringe K091377 Piston Syringe 21 CFR 880.580 Piston Syringe Class II Device FMF General Hospital
Reason for Submission	The basis of this submission is to modify the indications for use of the BD™ Flu+ Syringe.	
Device Description	The BD Flu+ Syringe is a sterile two-piece single use, sterile syringe with an integral needle. It allows for a variable dose up to 1 ml to be aspirated and injected. It is intended for general-purpose aspiration and injection of fluids from a vial or ampoule. The BD Flu+ syringe has been designed for low dead space to reduce medication waste. The BD Flu+ Syringe is a 1.0mL maximum dosage with 0.5mL and 1.0mL barrel marking and 0.25mL incremental markings. The Flu+ syringe is assembled with a pre attached needle in the following gauges and sizes:	

23G (0.6mm) x 1 inch (25mm)
25G (0.5mm) x 5/8 inch (16mm.)

	25G (0.5mm) x 1 inch (25mm)
Indications for Use	The BD™ Flu+ Syringe is intended for aspiration and injection of fluids.
Technological Characteristics	The subject devices are equivalent to the predicate devices in intended use, materials and performance characteristics.

Element of Comparison	Subject Device: BD™ Flu+ Syringe	Predicate Device BD™ Flu+ Syringe	Comparison
510(k) Number	K203359	K091377	N/A
Intended Use	Intended for aspiration and injection of fluids	Intended for aspiration and injection of the influenza vaccine	Different; Subject device is intended for general use
Syringe Type	2 Piece (barrel and plunger)	2 Piece (barrel and plunger)	Same
Dose Saving Feature	Low Dead Space/Volume	Low Dead Space/Volume	Same
Integrated Needle	Yes	Yes	Same
Dose Setting/Volumes	Variable dose scale markings with 1.0mL max delivery	Variable dose scale markings with 1.0mL max delivery	Same
Needle Size (Gauge x Length)	23G x 1” 25G x 1” 25G x 5/8”	23G x 1” 25G x 1” 25G x 5/8”	Same
Barrel Material	Plastic	Plastic	Same
Plunger Material	Plastic+Colorant (Blue, Orange)	Plastic+Colorant (Blue, Orange)	Same
Integrated Cannula	Stainless Steel	Stainless Steel	Same
Shield	Plastic	Plastic	Same
Adhesive	Epoxy	Epoxy	Same
Cannula Lubricant	Silicone	Silicone	Same
Sterilization	Ethylene Oxide (SAL 10^{-6})	Ethylene Oxide (SAL 10^{-6})	Same
Shelf Life	5 years	5 years	Same
Functional Testing:			

Leakage	ISO 7886-1	ISO 7886-1	Same
Dose Accuracy	ISO 7886-1	ISO 7886-1	Same
Dead Space	ISO 7886-1	ISO 7886-1	Same
Activation Forces	ISO 7886-1	ISO 7886-1	Same
Cannula Pull Force	ISO 7864	ISO 7864	Same
Shield Pull Force	BD Internal Requirement	BD Internal Requirement	Same
Scale Mark Permanency	BD Internal Requirement	BD Internal Requirement	Same
Biocompatibility Testing:			
Testing per ISO 10993:2018			
Cytotoxicity	ISO 10993-5 & USP <87>, Non-cytotoxic	ISO 10993-5 & USP <87>, Non-cytotoxic	Same
Sensitization	• LLNA: ISO 10993-10 & ASTM F2148 • Maximization: ISO 10993-11 Non-sensitizer	• LLNA: ISO 10993-10 & ASTM F2148 • Maximization: ISO 10993-11 Non-sensitizer	Same
Intracutaneous Reactivity	Per ISO 10993-10 & USP<88>, Non-irritant	Per ISO 10993-10 & USP<88>, Non-irritant	Same
Primary Dermal Irritation	ISO 10993-10	ISO 10993-10	Same
Acute Systemic Toxicity	ISO 10993-11 & USP<88>, Non-toxic	ISO 10993-11 & USP<88>, Non-toxic	Same
Pyrogenicity	Per ISO 10993-11:2017 & USP<151>, Non-pyrogenic	Per ISO 10993-11:2017 & USP<151>, Non-pyrogenic	Same
Extractables/ Leachables	Per ISO 10993-18:2005, Acceptable	Per ISO 10993-18:2005, Acceptable	Same
Hemolysis	Per ISO 10993-4, Non-hemolytic	Per ISO 10993-4, Non-hemolytic	Same

Performance Tests

BD has performed the following bench and biocompatibility testing on BD™ Flu+ Syringe. Modifications of the subject device's intended use does not affect the results of this analysis.

Bench Performance:

- Leakage (ISO 7886-1:2017)
- Dose Accuracy (ISO 7886-1:2017)

- Dead Space (ISO 7886-1:2017)
- Activation Forces (ISO 7886-1:2017)
- Cannula Pull Force (ISO 7864:2016)
- Shield Pull Force (BD Internal Requirement)
- Scale Mark Permanency (BD Internal Requirement)
- Package Integrity (ISO 11607-1:2010).

Material Biocompatibility Performance:
In accordance with ISO 10993-1, the Flu+ Syringe is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

Particulate matter testing was conducted in accordance with USP<788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterility, Shipping and Shelf-Life

Sterilization Method	Ethylene Oxide (ETO)
Sterilization Residuals	Maximum EO mg/device limit: 4mg/device Maximum ECH mg/device Limit: 9mg/device The above limits are acceptable per ISO 10993-7:2008
Validation Method	The sterilization process is validated in accordance with Standard EN ISO 11135-1."Sterilization of health care products-Ethylene oxide- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices". The sterilized product meets the

	requirements of EN 556 "Sterilization of Medical Devices - Requirements for Medical Devices to be Labelled Sterile ".
Pyrogenicity /Endotoxin Testing	Test methods are per USP 40-NF 35 monographs 85 (Bacterial Endotoxins Test) and 161 (Medical Devices Bacterial Endotoxin and Pyrogens Test).

Packaging integrity testing, after environmental conditioning are simulated transportation in accordance with ISO 11607-1:2010 and 11135:2014, was conducted on the final packaged, and sterile device. All packaging deemed acceptable for protection of product and sterility maintenance.

Shelf Life of 5 years is validated using the FDA recognized standards ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

The subject device continue to meet all the predetermined acceptance criteria for the above-listed performance tests, demonstrating substantial equivalence to the predicate device.

Clinical Testing	Clinical testing was not required for this submission
Summary of Substantial Equivalence	The BD™ Flu+ Syringe is substantially equivalent to the predicate device in principles of operation, technology, design, materials and performance.