December 5, 2023

BD
Michelle Bowerman
Director, Regulator Affairs
7 Loveton Cir.
Sparks, MD 21152 USA

Re: K232434
Trade/Device Name: BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test system
Regulatory Class: Class II
Product Code: PSZ
Dated: September 6, 2023
Received: September 7, 2023

Dear Michelle Bowerman:

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 and Part 809); 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,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2023.12.05 13:03:32 -05'00'

Silke Schlottmann, Ph.D.
Deputy Branch Chief
Bacteriology Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232434.S001

Device Name
BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit

Indications for Use *(Describe)*
The BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive, and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010–2011 Season, and Composition of the 2011–2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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

DATE PREPARED: August 11, 2023

SUBMITTED BY:
BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Cir.
Sparks, MD 21152
Establishment Registration Number: 1119779

CONTACT NAME:
Primary Contact:
Michelle Bowerman
Director, Regulatory Affairs
Tel: (269) 254-4802
Email: michelle.bowerman@bd.com

PROPRIETARY NAME: BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit

COMMON NAME: Devices Detecting Influenza A, B, and C Virus Antigens

REGULATION INFORMATION:

Regulatory Section	21 CFR 866.3328
Classification Name	Devices Detecting Influenza A, B, and C Virus Antigens
Device Class	Class 2
Panel	Microbiology
Product Code	PSZ

PREDICATE DEVICE: BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K223016)

DEVICE ESTABLISHMENT:
Becton, Dickinson and Company
7 Loveton Cir.
Sparks, MD 21152
Registration Number: 1119779

INTENDED USE

The BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive, and it is recommended that these results be

confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the *Morbidity and Mortality Weekly Report* from the CDC entitled "Update: Influenza Activity—United States, 2010–2011 Season, and Composition of the 2011–2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

DEVICE DESCRIPTION

A. Summary

The BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal and nasal swabs of symptomatic patients. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. It is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single test device. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other management decisions. All negative test results should be confirmed by another methodology, such as a nucleic acid-based method.

BD Veritor™ System Flu A+B test devices are interpreted by a BD Veritor™ Plus Analyzer. When using the BD Veritor™ Plus Analyzer, workflow steps depend on the selected operational mode and the Analyzer configuration settings. In **Analyze Now mode**, the instrument evaluates assay devices after manual timing of their development. In **Walk Away mode**, devices are inserted immediately after application of the specimen, and timing of assay development and analysis is automated.

B. Test Principle

There are no changes to the test principle since the assay was cleared under K223016. The modifications described in this submission do not change the test principle. The following is the principle of the test as stated in K223016.

The BD Veritor™ System Flu A+B CLIA-Waived Kit is an immuno-chromatographic assay for detection of influenza A and B viral antigens in samples processed from respiratory specimens. The viral antigens detected by the BD Flu A+B test are nucleoprotein, not hemagglutinin (HA) or neuraminidase (NA) proteins. Flu viruses are prone to minor point mutations (i.e., antigenic drift) in either one or both of the surface proteins (i.e., HA or NA). The BD Flu A+B test is not affected by antigenic drift or shift because it detects the highly conserved nucleoprotein of the influenza viruses. To perform the test, the patient specimen swab is treated in a supplied reaction tube prefilled with a lysing agent that serves to expose the target viral antigens, and then expressed through a filter tip into the sample well on a BD Veritor™ Flu A+B test device. Any influenza A or influenza B viral antigens present in the specimen bind to anti-influenza antibodies conjugated to colloidal gold micro-particles on the BD Veritor™ Flu A+B test strip. The antigen-conjugate complex then migrates across the test strip to the capture zone and reacts with either Anti-Flu A or Anti-Flu B antibodies that are immobilized on the two test lines on the membrane.

The BD Flu A+B test device shown in **Figure 1** is designed with five spatially distinct zones including positive and negative control line positions, separate test line positions for the target analytes, and a background zone. The test lines for the target analytes are labeled on the test device as 'A' for flu A position, and 'B' for flu B position. The onboard positive control ensures the sample has flowed correctly and is indicated on the test device as 'C'. Two of the five distinct zones on the test device are not labeled. These two zones are an onboard negative control line and an assay background zone. The active negative control feature in each test identifies and compensates for specimen-related, nonspecific signal generation. The remaining zone is used to measure the assay background.

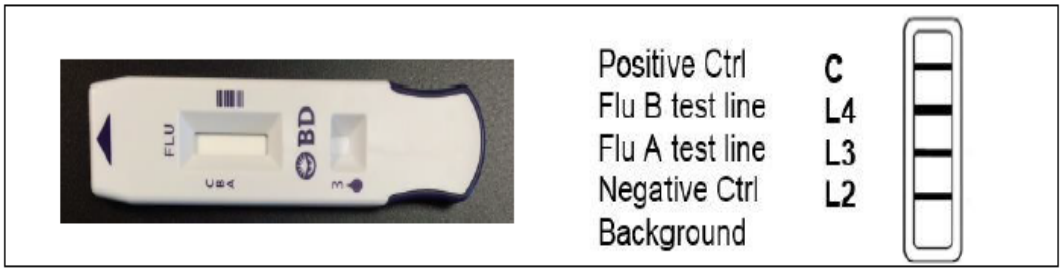


Figure 1: BD Veritor™ Flu A+B Assay Device

C. Flu A+B CLIA Waived Kit Contents

There are no changes to the contents of the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (Catalog # 256045) since the assay was cleared under K223016. The modifications described in this submission do not change the contents of the subject device. **Table 1** summarizes the contents in provided in the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (Catalog # 256045).

Table 1: Contents of the Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit

Component	Quantity	Description of Component
BD Veritor™ System Flu A+B Test Devices	30 Test Devices	Foil pouched device containing one reactive strip. Each strip has two test lines of antibodies specific to either influenza A or influenza B viral antigen, and positive and negative control lines.
RV Reagent D	30 tubes with 400 µL reagent	Detergent with < 0.1% sodium azide (preservative).
Flexible minitip flocked swab	30 each	Swab for nasopharyngeal or nasal collection.
Control A+/B-	1 each	Flu A positive and Flu B negative control swab, influenza A antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide.
Control B+/A-	1 each	Flu B positive and Flu A negative control swab, influenza B antigen (inactive recombinant nucleoprotein) with < 0.1% sodium azide.

D. Instrumentation

The BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit is intended for use with the BD Veritor™ Plus Analyzer.

The Analyzer is a digital immunoassay instrument that uses a reflectance-based measurement method and applies assay specific algorithms to determine the presence or absence of the target analyte. The Analyzer supports the use of different assays by reading an assay-specific barcode on the test device. Depending on the configuration chosen by the operator, the instrument communicates status and results to the operator via a liquid crystal display (LCD) on the instrument, a connected printer, or through a secure connection to the facility's information system.

In the case of the Flu A + B test, the BD Veritor™ Plus Analyzer subtracts nonspecific signal at the negative control line from the signal present at both the Flu A and Flu B test lines. If the resultant line signal is above a pre-selected assay cutoff, the specimen scores as positive. If the resultant line signal is below the cutoff, the specimen scores as negative. Use of the active negative control feature allows the BD Veritor™ Plus Analyzer to correctly interpret test results that cannot be scored visually because the human eye is unable to accurately perform the subtraction of the nonspecific signal. The measurement of the assay background zone is an important factor during test interpretation as the reflectance is compared to that of the control and test zones. A background area that is white to light pink indicates the device has performed correctly.

The instrument does not require calibration. A BD Veritor™ Plus Analyzer can be identified by the image in **Figure 2**.

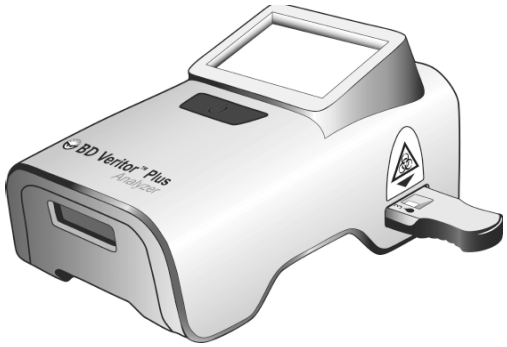


Figure 2. BD Veritor™ Plus Analyzer

The BD Veritor™ Plus Analyzer has the flexibility of an optional bar code scanning module and cellular connectivity designed to facilitate record keeping as well as the addition of a "Walk Away" workflow mode. Depending on the configuration chosen by the operator, the BD Veritor™ Plus Analyzer communicates status and results to the operator via a liquid crystal display (LCD) on the instrument, a connected printer, or through a secure connection to the facility's information system.

Table 2 lists the components that are included with the BD Veritor™ Plus Analyzer, which is purchased separately from the BD Veritor™ assays.

Table 2: BD VeritorTM Plus Analyzer Components

BD Veritor™ Plus Analyzer	1 each	Portable, rechargeable instrument for interpretation of BD Veritor™ System test devices
Instructions for Use	1 each	Printed instructions for use
USB Port Unlock Label	1 each	Adhesive label used to unlock the USB port
Compact AC power adapter with blades for USA, Japan, UK, and EU	1 each	Used to charge the internal rechargeable battery power source.
BD Veritor™ Verification Cartridge	1 each	Used to verify the proper functionality of the Analyzer.

The BD Veritor™ Analyzer can be used with the optional accessories such as the BD Veritor™ InfoWiFi and the BD Veritor™ Plus Connect.

There are no changes to the assay cut-off values, analyzing algorithm, assay barcoding or accessories to the Analyzer since K223016.

DESCRIPTION OF THE CHANGES

This traditional 510(k) is submitted for modifications to the BD Veritor™ Plus Analyzer previously cleared with the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit (K223016).

The Analyzer was modified to add a plastic shield to the Analyzer's enclosure and in front of the liquid crystal display (LCD) screen to protect the screen from being damaged when a high electrostatic discharge (ESD) voltage is applied. The main printed circuit board assembly (PCBA) was modified to add enhanced ESD and battery protection. The modified Analyzer was tested and demonstrated compliance with the following standards:

Safety Requirements for Electrical Equipment	IEC 61010-1:2010, IEC 61010-1:2010/AMD 1:2016 IEC 61010-2-101:2018 for use in conjunction with IEC 61010-1:2010, AMD 1:2016
Electromagnetic compatibility and electrical safety	EN IEC 61326-1:2020 EN IEC 61326-2-6:2021 EN 60601-1-2:2015 + A1: 2021 (the equivalence of ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021])

A new firmware (v6.00) was developed to support the Analyzer's new hardware features including switch monitoring, power path monitoring and control. The Instructions for Use for the BD Veritor™ Plus Analyzer will be updated to reflect conformance to the electromagnetic compatibility and electrical safety standards.

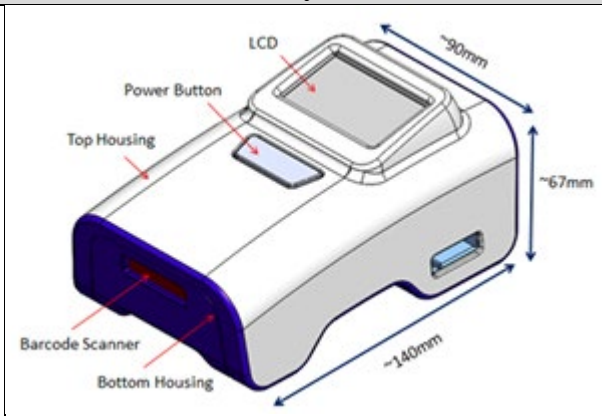
There are no changes to the subject device's intended use, kit components, or technological characteristics.

Table 3 provides a comparison between previously cleared device and the modified device.

Table 3: Comparison of Predicate Device to Modified Device

Feature	**BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit (K223016)**	**BD Veritor™ System for Rapid Detection of Flu A+B CLIA Waived Kit (K232434.S001)**
Intended Use	The BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The BD Veritor™ System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor™ System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B	Same

	viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive, and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens. Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	
Specimen Types	Nasal and nasopharyngeal swabs	Same
Assay Technology	Immunochromatographic	Same
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially defined test and control line positions, interprets the results using a scoring algorithm and reports a	Same

	positive, negative or invalid result on the LCD screen based on pre-set thresholds.	
Instrument – BD Veritor™ Plus Analyzer		
Appearance and dimensions		Same
Intended use	For use with BD Veritor™ System test devices	Same
LCD Screen	Original	Shield added to LCD screen
Printed Circuit Board Assembly	Original	Enhanced ESD and battery protection circuitry added
Electromagnetic compatibility and electrical safety	IEC 61326-1:2012 IEC 61326-2-6:2012 IEC 60601-1-2 ed 4.0:2014	EN IEC 61326-1:2020 EN IEC 61326-2-6:2021 ANSI AAMI IEC 60601-1-2:2014 [including Amendment 1 (2021)]
Firmware	Version v5.70	Version v6.00
Firmware functional verification	Verification cartridge supplied with each Analyzer	Same
Assay type determination	Internal camera reads barcode on test device	Same
Lifetime	10,000 tests 24 months from first use 34 months from date of manufacture	Same
Optional modules for data capture and transmission	InfoScan: reads specimen identification, operator identification, reagent lot information, reagent expiration date, and modifying the on-screen display language; download test information to a connected computer over a USB connection. InfoWiFi: same functional features as the InfoScan. InfoWiFi adds wireless	Same

	communication capability through a secure connection to the facility's information system.	
Assay workflow options	Analyze Now mode: Assay device is prepared with processed patient sample; user manually times the assay development and inserts assay device when development time is complete. Walk Away mode: Assay device is prepared with processed patient sample, inserted into the Analyzer immediately. Assay development is automatically timed by the instrument and result is displayed when development time is complete.	Same
Electrical		
Batteries	Lithium-ion rechargeable battery	Same
AC power adapter	To charge the lithium-ion battery and/or operate the analyzer from facility power	Same
Firmware		
Assay positivity algorithm	Original	Same
Assay cutoff thresholds	Original	Same
Cybersecurity controls	To meet requirements for data privacy and anti-hacking protection	Same
USB On-The-Go port	To connect to printer or to a computer to display or print results. Input firmware or menu updates from flash drive.	Same

SUBSTANTIAL EQUIVALENCE

In accordance with FDA's Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (July 28, 2014),* the modified device is substantially equivalent to the legally marketed device as described in K223016. The rationale for determination of substantial equivalence is based on the Guidance's' 510(k) Decision-Making Flowchart and described below.

- The predicate device, BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit, is a legally marketed device by BD.
- The modified device has the same intended use as the predicate device.
- The modified device has the same technological characteristics as the predicate device. The changes made to the Analyzer do not change the technological characteristics of the predicate device. There are no changes to the kit components of the device or to the workflow of performing the assay.
- The changes do not raise different questions of safety and effectiveness. Testing was performed and demonstrated compliance to:

Safety Requirements for Electrical Equipment	IEC 61010-1:2010, IEC 61010-1:2010/AMD 1:2016 IEC 61010-2-101:2018 for use in conjunction with IEC 61010-1:2010, AMD 1:2016
Electromagnetic compatibility and electrical safety	EN IEC 61326-1:2020 EN IEC 61326-2-6:2021 EN 60601-1-2:2015 + A1: 2021 (the equivalence of ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021])

- ***Instrument EMI/ESD:*** No EMI nor ESD susceptibility was observed during compliance testing. Non-clinical testing results verified that the Analyzer device functionalities remain the same and operations and performance of the Analyzer were not impacted.
- ***Analytical Performance:*** There have been no changes to the analytical performance of the BD Veritor™ System for Rapid Detection of Flu A+B CLIA-Waived Kit since the assay was last cleared in K180438. The modifications to the Analyzer do not have an impact on the assay-specific analytical performance.
- ***Clinical Performance:*** Clinical performance testing was not required because the changes made to the Analyzer do not have an impact on the assay-specific clinical performance.

Conclusion: In conclusion, the claim of substantial equivalence is based on the determination that the modifications to the Analyzer do not result in a new intended use or technological performance of the assay. The device is safe and as effective as the legally marketed device (K223016) and does not raise different questions of safety and effectiveness.