October 27, 2026

Becton, Dickinson and Company
David Lee
Staff Regulatory Affairs Specialist
7 Loveton Cir.,
Sparks, MD 21152, USA

Re: K261379/CW260015
Trade/Device Name: BD Veritor System for SARS-CoV-2
Regulation Number: 21 CFR 866.3982
Regulation Name: Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings
Regulatory Class: Class II
Product Code: QVF
Dated: May 1, 2026
Received: May 4, 2026

Dear David 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JOSEPH BRIGGS -S

Joseph Briggs, Ph.D.
Deputy Division Director
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)*
K261379

Device Name
BD Veritor System for SARS-CoV-2

Indications for Use *(Describe)*

The BD Veritor System for SARS-CoV-2 is a chromatographic digital immunoassay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic). The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the BD Veritor System for SARS-CoV-2 and followed up with a molecular test.

A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established between April 2024 and August 2024 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. Performance characteristics may vary with newly emerging SARS-CoV-2 virus variants.

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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510(k) Summary

BD Veritor™ System for SARS-CoV-2

Summary Preparation Date
October 23, 2026

Submitted by
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact
David Lee
Staff Regulatory Affairs Specialist
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Device Trade Names
BD Veritor™ System for SARS-CoV-2

Common Names
Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings

Regulatory Information

Regulation section:
21 CFR 866.3982 - Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings

Classification
Class II

Panel
Microbiology

Product Code(s)
QVF

Predicate Device
BD Veritor™ System for SARS-CoV-2 (K243872)

Device Establishment

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Registration Number: 1119779

Standards/Guidance Documents

- CLSI EP25 2nd Edition Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
- ISO 14971 Third Edition 2019-12 – Medical devices – Application of risk management to medical devices
- ISO 15223-1 Fourth edition 2021-07 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1 General requirements
- ISO 20417 First edition 2021-04 Corrected version 2021-12 - Medical devices - Information to be supplied by the manufacturer

Intended Use

The BD Veritor™ System for SARS-CoV-2 is a chromatographic digital immunoassay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic). The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the BD Veritor™ System for SARS-CoV-2 and followed up with a molecular test.

A negative test result is presumptive, and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Performance characteristics for SARS-CoV-2 were established between April 2024 and August 2024 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. Performance characteristics may vary with newly emerging SARS-CoV-2 virus variants..

Special Conditions for Use Statement

For Prescription Use only
For *in vitro* diagnostic use only

Special Instrument Requirements

BD Veritor™ System for SARS-CoV-2 is performed on BD Veritor™ Plus Analyzer for result interpretation.

Device Description

The BD Veritor™ System for SARS-CoV-2 is a rapid chromatographic digital immunoassay for the direct detection of the presence or absence of SARS-CoV-2 antigens in anterior swab specimens taken from patients with signs and symptoms who are suspected of COVID-19. The test is intended for interpretation in both laboratory and near patient testing environments only with the BD Veritor™ Plus Analyzer Instrument. The test is not intended to be interpreted visually.

Test Principle

The BD Veritor™ System for SARS-CoV-2 is a rapid (approximately 15 minutes) chromatographic digital immunoassay for the direct detection of the presence or absence of SARS-CoV-2 antigens in respiratory specimens taken from patients with signs and symptoms who are suspected of COVID-19. The test is intended for interpretation in both laboratory and near patient testing environments only with the BD Veritor™ Plus Analyzer Instrument. The test is not intended to be interpreted visually.

Procedures to evaluate test devices depend on the BD Veritor™ Plus Analyzer workflow configuration chosen. 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. Additionally, connection of a BD Veritor™ Plus Analyzer to a printer or IT system is possible if desired. Additional result documentation capabilities are possible with the integration of a BD Veritor™ barcode scanning enabled module.

The BD Veritor™ System consists of a dedicated opto-electronic interpretation instrument and immunochromatographic assays for the qualitative detection of antigens from pathogenic organisms in samples processed from respiratory specimens.

The BD Veritor™ System for SARS-CoV-2 is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19 by their healthcare provider.

- When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to biotinylated antibodies and antibodies conjugated to detector particles in the test strip.
- The biotinylated antibody-antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of streptavidin bound on the membrane.
- A positive result is determined by the BD Veritor™ Plus Analyzer when antigen-conjugate is deposited at the Test "T" position and a control conjugate is deposited at the Control "C" position on the assay device.
- The instrument analyzes and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective result.

The Analyzer uses a proprietary algorithm which subtracts nonspecific signal at the negative control line from the signal present at the test line. If the resultant test line signal is above a preselected cutoff, the specimen is scored as positive. If the resultant test line signal is below the cutoff, the specimen is scored as negative. Use of the active negative control feature allows the BD Veritor™ System 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 Analyzer measures the amount of light reflected from various zones along the assay strip. The measurement of the assay background zone is an important factor during the test interpretation as the reflectance value is compared to that of the control and test zones. The instrument analyzes the reflectance data to provide the proper test interpretation

Substantial Equivalence

Indication for Use Comparison

The Intended Use and Indication of Use of the BD Veritor™ System for SARS-CoV-2 is not changing as a result of the modification described in this 510(k) submission. The proposed modification is limited to an update to the Instructions for Use (IFU) and Quick Reference Guide (QRG) to extend the specimen stability supported by the new data. This change does not alter the intended use, patient population, specimen type or clinical application of the device.

Technological Comparison

BD Veritor™ System for SARS-CoV-2 has the same technological characteristics as the predicate device BD Veritor™ System for SARS-CoV-2 (K243872). Both the subject and predicate device are lateral flow immunoassay intended for point-of-care use and utilize the same design, materials, chemical compositions, and principle of operation. The device use identical assay components and the same instrument, BD Veritor™ Plus Analyzer, for result interpretation.

The proposed modification is limited to an update to the labeling to extend specimen stability under defined storage conditions. There have been no changes to device design, reagents, formulation, manufacturing process, software, or operating principles.

Performance data generated to support the extended specimen stability demonstrates that the device continues to meet its performance specification and operates in the same manner as the predicate device..

Table 1 - BD Veritor™ System for Rapid Detection of SARS-CoV-2 Substantial Equivalence Comparison

Device and Predicate Device:	Device	Predicate (K243872)
Device Trade Name	BD Veritor™ System for SARS-CoV-2	Same

General Device Characteristic Similarities		
Intended Use / Indications for Use	The BD Veritor™ System for SARS-CoV-2 is a chromatographic digital immunoassay for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic). The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the BD Veritor™ System for SARS-CoV-2 and followed up with a molecular test. A negative test result is presumptive and does not preclude SARS-CoV-2 infection; it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with other bacteria or viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established between April 2024 and August 2024 when SARS-CoV-2 Omicron was the predominant SARS-CoV-2 variant in circulation. Performance characteristics may vary with newly emerging SARS-CoV-2 virus variants.	Same
Regulation Number	21 CFR 866.3982	Same
Indication Type	In vitro diagnostic	Same
Intended Use Population	Individuals with symptoms of COVID-19	Same
Intended Use Setting	Point-of-Care	Same
Specimen Type	Direct anterior nasal swab	Same
Analyte	SARS-CoV-2 nucleocapsid protein	Same

Test type	Lateral flow immunochromatographic	Same
Test result Type	Qualitative	Same
Test Time	Approx. 15 minutes	Same
Instrumentation	BD Veritor™ Plus Analyzer	Same
Result Interpretation	Instrument read - BD Veritor™ Plus Analyzer scans the test strip and analyzes the reflectance data to provide the proper test interpretation. The Analyzer displays the test results (Positive, Negative, or Invalid) on the screen.	Same
General Device Characteristics Differences		
Specimen Stability	Freshly collected specimens should be processed as soon as possible after collection, but no later than 24 hours when stored in a sterile container at −20 °C to 30 °C. It is essential that correct specimen collection and preparation methods be followed.	Freshly collected specimens should be processed as soon as possible after collection, but no later than one hour when stored at room temperature. Swab samples that will be stored at 2° to 8 °C or at -20 °C for 12 hours should be stored in a sterile container. It is essential that correct specimen collection and preparation methods be followed

Analytical Performance

Specimen Integrity

Negative samples using pooled negative matrix from nasal swab eluted in FTA buffer and low positive contrived samples using SARS-CoV-2 virus tested at 2x LoD concentration with negative clinical matrix were prepared for the specimen stability study. Swabs were spiked with 50 µL of each sample and exposed to various storage conditions. Once the test sample swabs were prepared, they were placed into sterile tubes and transferred to a temperature chamber set to the test specified condition. The swabs were tested in 5 replicates for each exposure time. The BD Veritor™ System for SARS-CoV-2 produces acceptable results when a sample on swab and extracted specimen is stored at the tested temperatures and durations:

- Sample on swab and extracted specimen stored at 30 °C for up to15 minutes.
- Sample on swab and extracted specimen stored at refrigerated temperature 4 °C for up to 24 hours.
- Sample on swab and extracted specimen stored at 35 °C for up to 24 hours
- Sample on swab and extracted specimen stored frozen at -20 °C for up to 24 hours.
- Sample on swab and extracted specimen stored at 30 °C for up to 24 hours.

The results support a storage claim of 24 hours for unprocessed specimens when stored at −20 °C to 30 °C when stored in a sterile container.

Conclusion

Performance data support the proposed extension of specimen stability. The modification does not alter the intended use, technological characteristics, safety, or effectiveness of the device. Therefore, the BD Veritor™ System for SARS-CoV-2 is substantially equivalent to the predicate device, K243872.