October 22, 2026

Cepheid
% Riva Dill-Garlow
Regulatory Affairs Senior Specialist – New Product Development
Cepheid
904 Caribbean Dr.
Sunnyvale, California 94089

Re: K263333
Trade/Device Name: Xpert Xpress CoV-2/Flu plus
Regulation Number: 21 CFR 866.3981
Regulation Name: Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test
Regulatory Class: Class II
Product Code: QOF, OOI
Dated: September 22, 2026
Received: September 22, 2026

Dear Riva Dill-Garlow:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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)*
K263333

Device Name
Xpert Xpress CoV-2/Flu plus

Indications for Use *(Describe)*
The Xpert Xpress CoV-2/Flu plus test, performed on the GeneXpert Instrument Systems, is an automated multiplexed real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for use in the simultaneous in vitro qualitative detection and differentiation of severe acute respiratory syndrome coronavirus (SARS-CoV-2), influenza A and influenza B viral RNA in nasopharyngeal swab and anterior nasal swab specimens collected from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, and influenza B can be similar.

The Xpert Xpress CoV-2/Flu plus test is intended for use in the differential detection of SARS-CoV-2, influenza A and/or influenza B RNA and aids in the diagnosis of COVID-19 and/or influenza infections if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, and influenza B viral RNA are generally detectable in nasopharyngeal swab and anterior nasal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent (s) detected by the Xpert Xpress CoV-2/Flu plus test may not be the definite cause of the disease.

Negative results do not preclude SARS-CoV-2, influenza A and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

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
for
Xpert Xpress CoV-2/Flu *plus*

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1. 510(k) Summary

As required by 21 CFR Section 807.92(c).

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (408) 541-4191
Contact:	Riva Dill-Garlow
Date of Preparation:	September 22,2026

Device:

Trade name	Xpert® Xpress CoV-2/Flu *plus*
Common name	Xpert Xpress CoV-2/Flu *plus*
Type of Test	Qualitative real-time reverse transcription polymerase chain reaction (RT-PCR) and detection test
Regulation number Classification name Product code	21 CFR 866.3981, Multi-Target Respiratory Specimen Nucleic Acid Test Including SARS-CoV-2 and Other Microbial Agents. QOF 21 CFR 862.2570, Real Time Nucleic Acid Amplification System, OOI
Classification Advisory Panel	Microbiology (83)
Prescription Use	Yes
Predicate Device Assay:	Xpert® Xpress CoV-2/Flu/RSV *plus* (K250995)

1.1 Device Description

The Xpert Xpress CoV-2/Flu *plus* test is an automated *in vitro* diagnostic, simple point of care (POC) test developed by Cepheid for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Flu A and Flu B viral RNA in nasopharyngeal swab (NPS) and anterior nasal swab (NS) specimens collected from individuals showing signs and symptoms of respiratory viral infection.

The Xpert Xpress CoV-2/Flu *plus* test is performed on GeneXpert Xpress System, which consist of a GeneXpert IV instrument that executes sample preparation, nucleic acid amplification and real-time fluorescent signal detection for the tests, and a GeneXpert Hub with preloaded GeneXpert Xpress software for running the tests and viewing the test results. The GeneXpert Hub accessory integrates the computer, touchscreen monitor and barcode scanner. Each of the GeneXpert modules in the GeneXpert IV instrument can perform independent sample preparation and testing. The GeneXpert Xpress System requires the use of single-use disposable cartridges that hold the RT-PCR reagents and host sample purification, nucleic acid amplification, and detection of the target sequences. Because the cartridges are self-contained, cross-contamination between samples is minimized.

The Xpert Xpress CoV-2/Flu *plus* test cartridge includes reagents for the detection of SARS-CoV-2, Flu A and Flu B viral RNA from NPS and NS specimens. The primers and probes in the Xpert Xpress CoV-2/Flu *plus* test are designed to amplify and detect unique sequences in the genes that encode the following proteins: SARS-CoV-2 nucleocapsid (N), SARS-CoV-2 envelope (E), SARS-CoV-2 RNA-dependent RNA polymerase (RdRP), influenza A matrix (M), influenza A basic polymerase (PB2), influenza A acidic protein (PA), influenza B matrix (M) and influenza B non-structural protein (NS). A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert Xpress System. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The Xpert Xpress CoV-2/Flu *plus* test is designed for use with NPS or NS specimens collected with nylon flocked swabs and placed into viral transport medium (VTM), Universal Transport Medium (UTM) or eNAT®. The ancillary specimen collection kits, swabs and transport media verified and/or validated for use with the Xpert Xpress CoV-2/Flu *plus* test included:

- **Nasopharyngeal Sample Collection Kit for Viruses**
    - Copan UTM® 3C057N (Flexible Minitip Flocked Swab with UTM® Medium without Beads)
    - Copan eNAT® Molecular Collection and Preservation Medium P/N 6U074S01 (Flexible Minitip Flocked Swab with eNAT® Medium)

- Becton Dickinson Universal Viral Transport Kit P/N 220531 (Flexible Minitip Flocked Swab with UVT Medium)

- **Nasal Sample Collection Kit for Viruses**
  - Copan UTM® 3C064N (Regular Flocked Swab with UTM® Medium without Beads)
  - Copan eNAT® Molecular Collection and Preservation Medium P/N 6U073S01 (Regular Flocked Swab with eNAT® Medium)

- **Alternatively, swabs and transport media can be obtained separately:**
  - Nylon flocked swab (Copan P/N 502CS01, 503CS01)
  - Viral Transport Medium, 3 mL (Copan P/N 330C, 3C047N, BD Universal Transport Medium, Remel M4RT, or Remel M5)

These ancillary reagents allow NPS and NS specimens from patients to be collected, preserved and transported to laboratory prior to analysis with the Xpert Xpress CoV 2/Flu *plus* test.

1.2 Device Intended Use

The Xpert Xpress CoV-2/Flu *plus* test, performed on the GeneXpert® Instrument Systems, is an automated multiplexed real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for use in the simultaneous *in vitro* qualitative detection and differentiation of severe acute respiratory syndrome coronavirus (SARS-CoV-2), influenza A and influenza B viral RNA in nasopharyngeal swab and anterior nasal swab specimens collected from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, and influenza B can be similar.

The Xpert Xpress CoV-2/Flu *plus* test is intended for use in the differential detection of SARS-CoV-2, influenza A and/or influenza B RNA and aids in the diagnosis of COVID-19 and/or influenza infections if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, and influenza B viral RNA are generally detectable in nasopharyngeal swab and anterior nasal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent (s) detected by the Xpert Xpress CoV-2/Flu *plus* test may not be the definite cause of the disease.

Negative results do not preclude SARS-CoV-2, influenza A and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

1.3 Technical Characteristics

The Xpert Xpress CoV-2/Flu *plus* test has the same technological characteristics as the predicate device.

1.4 Substantial Equivalence

The Xpert Xpress CoV-2/Flu *plus*, is a modified version of the previously cleared Xpert Xpress CoV-2/Flu/RSV *plus* test. The purpose of this Special 510(k) submission is to support a design change in which the ADF is modified to mask the reporting of the RSV analyte.

Table 1 shows the similarities and **Table 2** shows the differences between the Xpert Xpress CoV-2/Flu *plus* and the predicate device. The differences between Xpert Xpress CoV-2/Flu *plus* test and predicate device do not raise different questions of safety and effectiveness.

Table 1. Similarities Between Xpert Xpress CoV-2/Flu *plus* and the Predicate Device

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Xpress CoV-2/Flu *plus*	**Xpert® Xpress CoV-2/Flu/RSV *plus*(K250995)**
Regulation	Same	21 CFR 866.3981 Devices to detect and identify nucleic acid targets in respiratory samples from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-analyte test
Product Code	Same	QOF Multi-target respiratory specimen nucleic acid test including SARS-CoV-2 and other microbial agents
Device Class	Same	II (Special Controls)
Technology/ Detection	Same	Real-time reverse transcription polymerase chain reaction (RT-qPCR)
Specimen Type	Same	• Nasopharyngeal swab (NPS) • Anterior nasal swab (NS)
Transport Media	Same	• Universal Transport Medium (UTM) / Viral Transport Medium (VTM) • eNAT

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Xpress CoV-2/Flu *plus*	**Xpert® Xpress CoV-2/Flu/RSV *plus*(K250995)**
Test Format	Same	Single Use
Automation	Same	Automated Nucleic Acid Extraction, Detection and Results Interpretation
Assay Results	Same	Qualitative
Internal Control	Same	Sample Processing Control (SPC) Probe Check Control (PCC)
Time to Result	Same	~ 36 min or less for sample preparation and RT-PCR
Instrument Systems	Same	Cepheid GeneXpert® Xpress System
GeneXpert Software	Same	GeneXpert Xpress software

Table 2. Differences Between Xpert Xpress CoV-2/Flu *plus* and the Predicate Device

Differences		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Xpress CoV-2/Flu *plus*	**Xpert® Xpress CoV-2/Flu/RSV *plus*** **(K250995)**
Intended Use	The **Xpert Xpress CoV-2/Flu** *plus* test, performed on the GeneXpert® Instrument Systems, is an automated multiplexed real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for use in the simultaneous *in vitro* qualitative detection and differentiation of severe acute respiratory syndrome coronavirus (SARS-CoV-2), influenza A and influenza B viral RNA in nasopharyngeal swab and anterior nasal swab specimens collected from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract	The **Xpert® Xpress CoV-2/Flu/RSV** *plus* test, performed on the GeneXpert® Xpress System, is an automated multiplexed real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for use in the simultaneous *in vitro* qualitative detection and differentiation of severe acute respiratory syndrome coronavirus (SARS-CoV-2), influenza A, influenza B**, and/or respiratory syncytial virus (RSV)** viral RNA in nasopharyngeal swab and anterior nasal swab specimens collected from individuals with signs and symptoms of respiratory tract infection. Clinical signs and

Differences		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Xpress CoV-2/Flu *plus*	**Xpert® Xpress CoV-2/Flu/RSV *plus* (K250995)**
	infection due to SARS-CoV-2, influenza A, and influenza B can be similar. The **Xpert Xpress CoV-2/Flu** *plus* test is intended for use in the differential detection of SARS-CoV-2, influenza A and/or influenza B RNA and aids in the diagnosis of COVID-19 and/or influenza infections if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, and influenza B viral RNA are generally detectable in nasopharyngeal swab and anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent (s) detected by the **Xpert Xpress CoV-2/Flu** *plus* test may not be the definite cause of the disease. Negative results do not preclude SARS-CoV-2, influenza A and/or influenza B infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.	symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, influenza B, and RSV can be similar. The **Xpert Xpress CoV-2/Flu/RSV** *plus* is intended for use in the differential detection of SARS-CoV-2, influenza A, influenza B **and/or RSV** RNA and aids in the diagnosis of COVID-19, influenza and/or RSV infections if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, influenza B, **and RSV** viral RNA are generally detectable in nasopharyngeal swab and anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent (s) detected by the **Xpert Xpress CoV-2/Flu/RSV** *plus* test may not be the definite cause of the disease. Negative results do not preclude SARS-CoV-2, influenza A virus, influenza B virus **and/or RSV infection**. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions.
Assay Targets	• SARS-CoV-2 • Influenza A • Influenza B	• SARS-CoV-2 • Influenza A • Influenza B • RSV

1.5 Summary of Performance Data

The performance of the Xpert Xpress CoV-2/Flu *plus* test was assessed by re-analyzing the verification and validation data previously generated with for the Xpert Xpress CoV-2/Flu/RSV *plus* test (K250995). Selected analytical (Competitive Interference Study and Potentially

Interference Substance Study) and clinical studies data generated with the original design (K250995) were reanalyzed using the modified ADF designed to mask the RSV analyte in the Xpert Xpress CoV-2/Flu *plus* test.

A comparison of the 84 test results from the Competitive Interference Study and 2571 test results from the Potentially Interfering Substances Study demonstrated that the number of valid test runs and non-determinate (ND) test results were the same, the test results for SARS-CoV-2, Flu A and Flu B were identical between the original ADF and the modified ADF. As intended, the RSV analyte was masked from the test result output with the Xpert Xpress CoV-2/Flu *plus* ADF.

Similarly, a comparison of the 5,380 test results from the Clinical Study also demonstrated that the number of valid test runs and ND test results were the same between the original ADF for Xpert Xpress CoV-2/Flu/RSV *plus* and the modified ADF with RSV analyte masked for Xpert Xpress CoV-2/Flu *plus*. There were no changes to any of the valid test results for SARS-CoV-2, Flu A, and Flu B. The reanalysis confirmed that RSV is masked from the test result output with modified ADF designed for the Xpert Xpress CoV-2/Flu *plus* test.

The assessment of the re-analysis results determined that the performance claims of the Xpert Xpress CoV-2/Flu *plus* test were not impacted by the modifications made to the predicate device.

1.6 Conclusion

The results of the re-analysis of selected verification and validation studies demonstrated that the Xpert Xpress CoV-2/Flu *plus* test when performed with a modified ADF is substantially equivalent to the original design of the Xpert Xpress CoV-2/Flu/RSV *plus* (K250995, the predicate device).