July 2,2026

Cepheid
Bansari Doshi
Regulatory Affairs Senior Specialist, New Product Development
904 Caribbean Dr.
Sunnyvale, California 94089

Re: K261867
Trade/Device Name: Xpert Carba-R
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: POC, PMY, OOI
Dated: June 4, 2026
Received: June 4, 2026

Dear Bansari Doshi:

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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility 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)*
K261867

Device Name
Xpert Carba-R

Indications for Use *(Describe)*
The Xpert Carba-R test, performed on the GeneXpert Instrument Systems, is a qualitative in vitro diagnostic test designed for the detection and differentiation of the blaKPC, blaNDM, blaVIM, blaOXA-48, and blaIMP gene sequences associated with carbapenem-non-susceptibility. The test utilizes automated real-time polymerase chain reaction (PCR).

The Xpert Carba-R test is intended as an aid to infection control in the detection of carbapenem-non-susceptible bacteria that colonize patients in healthcare settings. A negative Xpert Carba-R test result does not preclude the presence of other resistance mechanisms.

The Xpert Carba-R test is for use with the following sample types:

Pure Colonies
The test is performed on carbapenem-non-susceptible pure colonies of Enterobacterales, Acinetobacter baumannii, or Pseudomonas aeruginosa, when grown on blood agar or MacConkey agar. For testing pure colonies, the Xpert Carba-R test should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.

The identification of a blaIMP, blaNDM, or blaVIM metallo-beta-lactamase gene (i.e., the genes that encode the IMP, NDM, and VIM metallo-beta-lactamases, respectively) may be used as an aid to clinicians in determining appropriate therapeutic strategies for patients with known or suspected carbapenem-non- susceptible bacterial infections.

Rectal and Perirectal Swab Specimens
The test is performed on rectal and perirectal swab specimens from patients at risk for intestinal colonization with carbapenem-non-susceptible bacteria. Concomitant cultures are necessary to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for further confirmatory bacterial identification.

The Xpert Carba-R test, when performed on rectal and perirectal swab specimens, is not intended to guide or monitor treatment for carbapenem-non-susceptible bacterial infections or to determine infection from carbapenem-non-susceptible bacteria.

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 Carba-R

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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: Bansari Doshi, M.S.

Date of Preparation: June 05, 2026

Device:

Trade name	Xpert® Carba-R
Common name	Xpert Carba-R
Type of Test	Qualitative nucleic acid amplification test of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences associated with carbapenem-non-susceptibility in gram-negative bacteria obtained from rectal swab specimens, perirectal swab specimens, and bacterial isolates
Regulation number Classification name Product code	21 CFR 866.1640 Antimicrobial susceptibility test powder. POC (primary), PMY 21 CFR 862.2570, Real Time Nucleic Acid Amplification System, OOI
Classification Advisory Panel	Microbiology (83)
Prescription Use	Yes
Predicate Device Assay:	Xpert® Carba-R (K173263)

1.1 Device Description

The Xpert Carba-R test is an automated real-time polymerase chain reaction (PCR) *in vitro* diagnostic test for qualitative detection of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences from rectal or perirectal swab specimens or isolates of pure cultures of carbapenem-non-susceptibility gram-negative bacteria. The Xpert Carba-R test is intended as an aid for infection control for monitoring the spread of carbapenem-non-susceptible organisms in healthcare settings.

The Xpert Carba-R test is performed on the Cepheid GeneXpert® Instrument Systems (GeneXpert Dx, GeneXpert Infinity-48s, and GeneXpert Infinity-80 systems, and GeneXpert System with Touchscreen). The GeneXpert Instrument Systems platform automates sample preparation, amplification and real-time detection.

The GeneXpert Instrument Systems require the use of single-use, disposable cartridges (the Xpert Carba-R cartridges) that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained and specimens never come into contact with working parts of the instrument modules, cross-contamination between samples is minimized.

The Xpert Carba-R test cartridges contain reagents for the detection of *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are controls utilized by the GeneXpert Instrument System platform. The SPC is present to control for adequate processing of the target bacteria and to monitor the presence of inhibitors in the real-time PCR reaction to reduce the possibility of false negative results. The PCC verifies reagent rehydration, real-time PCR tube filling in the cartridge, probe integrity, and dye stability.

The single-use, multi-chambered fluidic cartridges are designed to complete sample preparation and real-time PCR for the detection of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences from rectal or perirectal swab specimens or isolates of pure cultures of carbapenem-non- susceptibility gram-negative bacteria in approximately 50 minutes. The GeneXpert Instrument Systems have 1 to 80 randomly accessible modules, depending upon the instrument, that are each capable of performing separate sample-processing and real-time PCR and RT- PCR tests. Each module contains a syringe drive for dispensing fluids (i.e., the syringe drive activates the plunger that works in concert with the rotary valve in the cartridge to move fluids between chambers), an ultrasonic horn for lysing cells or spores, and a proprietary I-CORE® thermocycler for performing real-time PCR and RT-PCR and detection.

Rectal or perirectal swab specimens or bacterial isolates from culture are placed into a sample reagent. The sample is transferred to the sample chamber of the disposable fluidic cartridge (the Xpert Carba-R cartridge). The user initiates a test from the system user interface and places the cartridge into the GeneXpert instrument platform, which performs hands-off real-time, multiplex PCR for detection of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences. The

results are automatically generated at the end of the process in a report that can be viewed and printed.

1.2 Device Intended Use

The Xpert® Carba-R test, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test designed for the detection and differentiation of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences associated with carbapenem-non-susceptibility. The test utilizes automated real-time polymerase chain reaction (PCR).

The Xpert Carba-R test is intended as an aid to infection control in the detection of carbapenem-non-susceptible bacteria that colonize patients in healthcare settings. A negative Xpert Carba-R test result does not preclude the presence of other resistance mechanisms.

The Xpert Carba-R test is for use with the following sample types:

Pure Colonies
The test is performed on carbapenem-non-susceptible pure colonies of Enterobacterales, *Acinetobacter baumannii*, or *Pseudomonas aeruginosa*, when grown on blood agar or MacConkey agar. For testing pure colonies, the Xpert Carba-R test should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.

The identification of a *bla*$_{IMP}$, *bla*$_{NDM}$, or *bla*$_{VIM}$ metallo-beta-lactamase gene (i.e., the genes that encode the IMP, NDM, and VIM metallo-beta-lactamases, respectively) may be used as an aid to clinicians in determining appropriate therapeutic strategies for patients with known or suspected carbapenem-non-susceptible bacterial infections.

Rectal and Perirectal Swab Specimens
The test is performed on rectal and perirectal swab specimens from patients at risk for intestinal colonization with carbapenem-non-susceptible bacteria. Concomitant cultures are necessary to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for further confirmatory bacterial identification.

The Xpert Carba-R test, when performed on rectal and perirectal swab specimens, is not intended to guide or monitor treatment for carbapenem-non-susceptible bacterial infections or to determine infection from carbapenem-non-susceptible bacteria.

1.3 Technical Characteristics

The Xpert Carba-R test has the same technological characteristics as the predicate device.

1.4 Substantial Equivalence

The purpose of this Special 510(k) submission is to support the labeling update of the "Summary of Subtypes Detected by Wet Testing or Predicted to be Detected Based on *In Silico* Analysis" table in the Instructions for Use (IFU). The update incorporates results from an updated *in silico*

analysis to ensure that the device labeling accurately reflects the intended variant detection performance.

Table 1 shows the similartities and differences between the modified Xpert Carba-R test and the previously cleared Xpert Carba-R (K173263, the predicate device).

Table 1. Comparison of Similarities and Differences Between Xpert Carba-R and the Predicate Device

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Carba-R Test (K261867)	**Xpert® Carba-R Test (K173263)**
Regulation	Same	**21 CFR 866.1640** Antimicrobial susceptibility test powder
Product Code	Same	POC System, Nucleic Acid Amplification Test, Dna, Antimicrobial Resistance Marker, Direct Specimen PMY System, Nucleic Acid Amplification Test, Dna, Carbapenem Non-Susceptible Gram Negative Organism, Colony OOI Real Time Nucleic Acid Amplification System
Device Class	Same	Class II
Technology/ Detection	Same	Fully automated nucleic acid amplification (DNA); real-time PCR
Intended Use	Same*	The Xpert® Carba-R Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test designed for the detection and differentiation of the *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences associated with carbapenem-non-susceptibility. The test utilizes automated real-time polymerase chain reaction (PCR). The Xpert Carba-R Assay is intended as an aid to infection control in the detection of carbapenem-non-susceptible bacteria that colonize patients in healthcare settings. A negative Xpert Carba-R Assay result does not preclude the presence of other resistance mechanisms.

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Carba-R Test (K261867)	**Xpert® Carba-R Test (K173263)**
		The Xpert Carba R Assay is for use with the following sample types: **Pure Colonies** The assay is performed on carbapenem-non-susceptible pure colonies of *Enterobacteriaceae*, *Acinetobacter baumannii*, or *Pseudomonas aeruginosa*, when grown on blood agar or MacConkey agar. For testing pure colonies, the Xpert Carba-R Assay should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing. The identification of a *bla*$_{IMP}$, *bla*$_{NDM}$, or *bla*$_{VIM}$ metallo-beta-lactamase gene (i.e., the genes that encode the IMP, NDM, and VIM metallo-beta-lactamases, respectively) may be used as an aid to clinicians in determining appropriate therapeutic strategies for patients with known or suspected carbapenem-non- susceptible bacterial infections. **Rectal and Perirectal Swab Specimens** The assay is performed on rectal and perirectal swab specimens from patients at risk for intestinal colonization with carbapenem-non-susceptible bacteria. Concomitant cultures are necessary to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for further confirmatory bacterial identification. The Xpert Carba-R Assay, when performed on rectal and perirectal swab specimens, is not intended to guide or monitor treatment for carbapenem-non-susceptible bacterial infections or to determine infection from carbapenem-non-susceptible bacteria.
Type of test	Same	Qualitative
Test Cartridge	Same	Disposable single-use, multi-chambered fluidic cartridge
Fluidics	Same	Self-contained and automated after specimen is added to the cartridge
Specimen Type	Same	Bacterial isolates from culture, rectal swab and perirectal swab specimens

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® Carba-R Test (K261867)	**Xpert® Carba-R Test (K173263)**
Probes	Same	TaqMan® Probes
Internal Controls	Same	• Sample Processing Control (SPC) • Probe Check Control (PCC)
DNA Target Sequence	Same	*bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{VIM}$, *bla*$_{OXA-48}$, and *bla*$_{IMP}$ gene sequences
Time to Result	Same	Approximately 50 minutes to results
Assay Format	Same	Amplification: PCR Detection: Fluorogenic target-specific hybridization
Interpretation of Test Results	Same	Automated (Diagnostic software)
Users	Same	Trained users
Instrument Systems	Same	Cepheid GeneXpert® Instrument Systems (GeneXpert Dx System, GeneXpert Infinity System, GeneXpert System with Touchscreen)
Software	Same	• GeneXpert Dx software • GeneXpert Xpertise software • Cepheid OS software
Labeling Differences		
Labeling – Variant Detection Information	*In silico* analysis of new variant gene sequences was carried out by querying the NCBI database current as of 2026	BLAST analysis was carried out by querying the NCBI database as of 2015

*The Intended Use is same as predicate device, except for minor terminology updates for consistency (replacement of "assay with "test") and alignment with current taxonomic terminology (updated from "*Enterobacteriaceae*" to "Enterobacterales").

1.5 Summary of Performance Data

The performance data to support an update to the "Summary of Subtypes Detected by Wet Testing or Predicted to be Detected Based on *In Silico* Analysis" table in the Instructions for Use (IFU) consisted of an updated *in silico* analysis based on current variant sequence data. The analysis evaluated primer and probe coverage for recently identified variants and demonstrated that the test is predicted to detect the variants as intended. Supplemental inclusivity testing was performed for selected variants to confirm the *in silico* predictions and the results were consistent with the *in silico* analysis.

The updated analyses support the IFU labeling changes only. No changes were made to the device design, and the updates do not impact the device performance, safety or effectiveness.

1.6 Conclusion

The modified Xpert Carba-R test has the same intended use and technological characteristics as the legally marketed predicate device (Xpert Carba-R; K173263), with only minor updates to the

Intended Use related to branding simplification and alignment with current taxonomic nomenclature. Performance data demonstrate that the modified device is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness.