October 25, 2024

Cepheid
Bansari Doshi
Regulatory Affairs Specialist
904 Caribbean Drive
Sunnyvale, California 94089

Re: K243070

Trade/Device Name:	Xpert SA Nasal Complete
Regulation Number:	21 CFR 866.1640
Regulation Name:	Antimicrobial Susceptibility Test Powder
Regulatory Class:	Class II
Product Code:	NQX, OOI
Dated:	September 27, 2024
Received:	September 27, 2024

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 System (QS) regulation (21 CFR §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 §807); labeling (21 CFR §801 and §809); medical device reporting (reporting of medical device-related adverse events) (21 CFR §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 §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 §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 §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)*
K243070

Device Name
Xpert® SA Nasal Complete

Indications for Use *(Describe)*
The Xpert® SA Nasal Complete test performed on the GeneXpert® Instrument Systems is a qualitative in vitro diagnostic test designed for detection of Staphylococcus aureus (SA) and methicillin-resistant Staphylococcus aureus (MRSA) from nasal swabs in patients at risk for nasal colonization. The test utilizes automated real-time polymerase chain reaction (PCR) to detect MRSA/SA DNA. The Xpert® SA Nasal Complete test is intended to aid in the prevention and control of MRSA/SA infections in healthcare settings. The Xpert® SA Nasal Complete test is not intended to diagnose, guide or monitor treatment for MRSA/SA infections, or provide results of susceptibility to methicillin. A negative result does not preclude MRSA/SA nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

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
for
Xpert SA Nasal Complete

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1 510(k) Summary

As required by 21 CFR Section 807.92.

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (408) 541-4191
Contact:	Bansari Doshi, M.S.
Date of Preparation:	September 27, 2024
Device:	
Trade name	Xpert® SA Nasal Complete
Common name	Xpert SA Nasal Complete
Type of Test	Nucleic Acid Amplification Test, DNA, *Staphylococcus aureus* (SA) and Methicillin-resistant *Staphylococcus aureus* (MRSA), qualitative
Regulation number:	21 CFR 866.1640
Classification name:	Antimicrobial susceptibility test powder
Product code:	NQX (primary), OOI
Classification Advisory Panel	Microbiology (83)
Prescription Use	Yes
Predicate Device Assay:	Xpert SA Nasal Complete (K100822)

1.1 Device Description

The Xpert SA Nasal Complete test is an automated *in vitro* diagnostic DNA test for the qualitative, simultaneous detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) directly from nasal swabs. The specimen is collected on a double swab, one of which is placed in a tube containing elution reagent. Following brief vortexing, the eluted material is transferred to different, uniquely-labeled chamber of the disposable fluidic cartridge (the Xpert SA Nasal Complete cartridge). The user initiates a test from the user interface of the GeneXpert® Instrument Systems and places the cartridge with sample into the GeneXpert® Instrument System platform, which performs hands-off real-time, multiplex polymerase chain reaction (PCR) for detection of *S. aureus* (including MRSA) DNA.

In the GeneXpert® Instrument Systems (comprised of the GeneXpert® Dx Systems, GeneXpert® System with Touchscreen, and GeneXpert® Infinity Systems), sample preparation, amplification, and real-time detection are all fully-automated and completely integrated. The platform requires the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.

Depending on the specific instrument, the GeneXpert® Instrument Systems may contain 1–80 modules, each of which are randomly accessible and capable of performing separate sample preparation and real-time 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 detection.

The Xpert SA Nasal Complete test kit includes reagents for the simultaneous detection of SA and MRSA targets. The primers and probes provided in the Xpert SA Nasal Complete test kit detects nucleic acid sequences of the staphylococcal protein A (*spa*), the gene for methicillin/oxacillin resistance (*mecA*), and staphylococcal cassette chromosome (SCC*mec*) inserted in the SA chromosomal *attB* site.

The Xpert SA Nasal Complete cartridge includes a sample processing control (SPC) to control for adequate processing of the target bacteria and to monitor the presence of inhibitor(s) in the PCR assay. The Probe Check Control (PCC) verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

The Xpert SA Nasal Complete test performed on the GeneXpert® Instrument Systems provides results in approximately 65 minutes.

Each instrument in the GeneXpert® Instrument family is equipped with a Windows OS-based personal computer that is preloaded with software applications for running the tests and viewing the results, as described in **Table 1**.

Table 1. Instrument Systems and Software in the GeneXpert® Instrument Family Members

Instrument Family Members	Instrument Systems	Systems Software	Instruments
GeneXpert® Instrument Systems	GeneXpert® Dx Systems	*GeneXpert Dx*	• GX-I† • GX-II • GX-II • GX-IV • GX-XVI
	GeneXpert® System with Touchscreen	*Cepheid OS*	• GX-II • GX-IV • GX-XVI
	GeneXpert® Infinity Systems	*GeneXpert Xpertise*	• GeneXpert Infinity-48s • GeneXpert Infinity-80

† No longer manufactured but is in circulation in the market

1.2 Device Intended Use

The Xpert SA Nasal Complete test performed on the GeneXpert® Instrument Systems is a qualitative *in vitro* diagnostic test designed for detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) from nasal swabs in patients at risk for nasal colonization. The test utilizes automated real-time polymerase chain reaction (PCR) to detect MRSA/SA DNA. The Xpert SA Nasal Complete test is intended to aid in the prevention and control of MRSA/SA infections in healthcare settings. The Xpert SA Nasal Complete test is not intended to diagnose, guide or monitor treatment for MRSA/SA infections, or provide results of susceptibility to methicillin. A negative result does not preclude MRSA/SA nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

1.3 Technical Characteristics

The Xpert SA Nasal Complete test has the same technological characteristics as the predicate device.

1.4 Substantial Equivalence

The purpose of this Special 510(k) submission is to modify the cleared, legally marketed device (Xpert SA Nasal Complete) to include the GeneXpert® Infinity Systems instruments (see Table 1 above). The Xpert SA Nasal Complete was originally cleared for use on the GeneXpert® Dx System (K100822). Both the GeneXpert Dx System and GeneXpert Infinity Systems are members of the instrument family "GeneXpert® Instrument Systems" which is now incorporated in the Intended Use/Indications for Use of this device. **Table 2** shows the similarities and **Table 3** shows the differences between the Xpert SA Nasal Complete test and predicate device. The differences between Xpert SA Nasal Complete test and predicate device do not raise different questions of safety and effectiveness.

Table 2. Similarities between Xpert SA Nasal Complete and the Predicate Device

Similarities		
Attribute	**Modified Device**	**Predicate (K100822)**
	Xpert® SA Nasal Complete	**Xpert® SA Nasal Complete**
Regulation	Same	**21 CFR 866.1640** Antimicrobial susceptibility test powder
Product Code	Same	NQX System, Nucleic Acid Amplification Test, DNA, Methicillin Resistant *Staphylococcus Aureus*, Direct Specimen OOI Real Time Nucleic Acid Amplification System
Device Class	Same	Class II
Purpose of Use	Same	Identification of MRSA and SA
Specimen	Same	Nasal swab
Test Technology	Same	Nucleic Acid (DNA) Amplification (real time PCR) for qualitative detection of *Staphylococcus aureus* (SA) and Methicillin-resistant *S. aureus* (MRSA) with specific primers and TaqMan probes Detection: Fluorogenic target-specific hybridization
Test Automation	Same	Fully-automated DNA extraction, detection, and results interpretation
Test Format	Same	Single-use in disposable, multi-chambered, fluidic cartridge
Test targets (*sequence*)	Same	• Staphylococcal protein A (*spa*) • Methicillin/oxacillin resistance (*mecA*) • Staphylococcal chromosomal cassette (*SCCmec*) insertion event into *S. aureus* chromosomal *attB* site
Internal Controls	Same	• Sample Processing Control (SPC) • Probe Check Control (PCC)
Intended Use environment	Same	Professional Use, by trained users
Test Access	Same	Prescription Use only

Table 3. Differences between Xpert SA Nasal Complete and the Predicate Device

Differences		
Attribute	**Modified Device**	**Predicate (K100822)**
	Xpert® SA Nasal Complete	**Xpert® SA Nasal Complete**
Time to Results	Approximately 65 minutes	Approximately 50 minutes
Intended Use / Indications for Use	The Xpert SA Nasal Complete **test** performed on the **GeneXpert® Instrument Systems** is a qualitative in vitro diagnostic test designed for detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus*	The Cepheid® Xpert SA Nasal Complete assay performed in the **GeneXpert® Dx System** is a qualitative in vitro diagnostic test designed for **rapid** detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) from

Differences		
Attribute	**Modified Device**	**Predicate (K100822)**
	Xpert® SA Nasal Complete	**Xpert® SA Nasal Complete**
	aureus (MRSA) from nasal swabs in patients at risk for nasal colonization. The test utilizes automated real-time polymerase chain reaction (PCR) to detect MRSA/SA DNA. The Xpert SA Nasal Complete **test** is intended to aid in the prevention and control of MRSA/SA infections in healthcare settings. The Xpert SA Nasal Complete **test** is not intended to diagnose, guide or monitor treatment for MRSA/SA infections, or provide results of susceptibility to methicillin. A negative result does not preclude MRSA/SA nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.	nasal swabs in patients at risk for nasal colonization. The test utilizes automated real-time polymerase chain reaction (PCR) to detect MRSA/SA DNA. The Xpert SA Nasal Complete assay is intended to aid in the prevention and control of MRSA/SA infections in healthcare settings. The Xpert SA Nasal Complete assay is not intended to diagnose, guide or monitor treatment for MRSA/SA infections, or provide results of susceptibility to methicillin. A negative result does not preclude MRSA/SA nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.
Instrument Systems	• GeneXpert Dx Systems • GeneXpert System with Touchscreen • GeneXpert Infinity-48s and Infinity-80 Systems	• GeneXpert Dx Systems • GeneXpert System with Touchscreen
Systems Software for instrument family	• GeneXpert Dx software • Cepheid OS software • Xpertise software	• GeneXpert Dx software • Cepheid OS software

1.5 Summary of Performance Data

The performance of the Xpert SA Nasal Complete test when used with the GeneXpert Infinity Systems instruments was assessed through verification studies, including a prepared cartridge hold time study and functional testing.

Hold time refers to the duration between the preparation of the cartridge (i.e., addition of sample) and the initiation of the test. The maximum acceptable hold time for a prepared cartridge was verified as 4 hours.

Functional testing was conducted using both contrived positive (MRSA added to negative matrix) and negative (negative matrix only) samples. Each target of the Xpert SA Nasal Complete test was analyzed, resulting in a reportable outcome. The study results showed 100% agreement of reportable results, with no statistically significant differences in Ct values observed between assay runs in instruments of the GeneXpert Dx Systems and GeneXpert Infinity Systems. This study demonstrated equivalent performance of the Xpert SA Nasal Complete test when performed on any member of the GeneXpert® Instrument Systems family.

The assessment of the results from these studies determined that the performance claims of the Xpert SA Nasal Complete test were not impacted by the modifications made to the predicate device.

1.6 Conclusion

The results of the verification studies demonstrated that the performance of the modified Xpert SA Nasal Complete test on the GeneXpert Infinity Systems is equivalent to the performance of the predicate device, the original Xpert SA Nasal Complete (K100822) and that the modifications proposed in K243070 have not changed the fundamental scientific technology of the predicate device.