February 21, 2025

Cepheid
Sruti Krishna
Regulatory Affairs Principal, New Product Development
904 Caribbean Drive
Sunnyvale, California 94089

Re: K250218
Trade/Device Name: Xpert FII & FV
Regulation Number: 21 CFR 864.7280
Regulation Name: Factor V Leiden DNA Mutation Detection Systems
Regulatory Class: Class II
Product Code: NPR, NPQ, OOI
Dated: January 24, 2025
Received: January 24, 2025

Dear Sruti Krishna:

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.

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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250218

Device Name
Xpert® FII & FV

Indications for Use *(Describe)*

The Xpert® FII & FV test is a qualitative in vitro diagnostic genotyping test for the detection of Factor II and Factor V alleles from sodium citrate or EDTA anticoagulated whole blood. The test is performed on the GeneXpert® Instrument Systems. This test is intended to provide results for Factor II (G20210A) and Factor V Leiden (G1691A) mutations as an aid in the diagnosis in individuals with suspected thrombophilia.

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

As required by 21 CFR Section 807.92(c).

Submitted by: Cepheid
904 Caribbean Drive
Sunnyvale, CA 90489
Phone number: (408) 541-4191
Contact : Sruti Krishna, Ph.D.
Date of Preparation : January 24, 2025

Device:

Trade Name:	Xpert® FII & FV
Common Name:	Xpert Factor II & Factor V
Type of Test:	Test, Factor II G20210A Mutations, Genomic DNA PCR
Regulation Number:	21 CFR 864.7280
Regulation Description:	Factor V Leiden DNA Mutation Detection Systems
Product Codes:	NPR (primary), NPQ, OOI
Classification:	Class II
Review Panel:	Pathology
Prescription Use:	Yes
Predicate Device:	Xpert FII & FV (K223046)

1. Device Description

Xpert FII & FV is an automated genotyping test for detecting Factor II and Factor V normal and mutant alleles directly from sodium citrate or EDTA anticoagulated whole blood specimens. Blood specimens are drawn into either sodium citrate or EDTA anticoagulant tubes. Following brief mixing of the sample, 50 µL of the blood sample is transferred to the bottom wall of the Sample opening of the Xpert FII & FV test cartridge. The user initiates a test from the system user interface and places the cartridge into the GeneXpert Instrument System.

The Xpert FII & FV test includes reagents for the detection of Factor II and Factor V normal and mutant alleles. The primers and probes in the Xpert FII & FV test determine the genotype of the Factor II gene (at position 20210) and/or the Factor V gene (at position 1691). The test includes a Sample Processing Control (SPC) to confirm adequate processing 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 GeneXpert Instrument Systems family is comprised of GeneXpert Dx System, GeneXpert Infinity System, and GeneXpert System with Touchscreen. The GeneXpert Instrument Systems automate and integrate sample processing, nucleic acid amplification and detection of the target sequences in simple or complex samples using real-time polymerase chain reaction (PCR). The systems consist of an instrument, computer or touchscreen, and preloaded software for running the tests and viewing the results. The GeneXpert Instrument Systems require 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.

The GeneXpert Instrument Systems have 1 to 80 modules (depending upon the instrument) that are each 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 FII & FV test performed on the GeneXpert Instrument Systems provides results in approximately 30 minutes.

2. Device Intended Use

The Xpert® FII & FV test is a qualitative *in vitro* diagnostic genotyping test for the detection of Factor II and Factor V alleles from sodium citrate or EDTA anticoagulated whole blood. The test is performed on the GeneXpert® Instrument Systems. This test is intended to provide results for Factor II (G20210A) and Factor V Leiden (G1691A) mutations as an aid in the diagnosis in individuals with suspected thrombophilia.

3. Technical Characteristics

The Xpert FII & FV test has the same technological characteristics as the predicate device.

4. Substantial Equivalence

The purpose of this Special 510(k) submission is to support the removal of the following erroneous limitation statement from the Instructions for Use of an on-market device (Xpert FII & FV): “The performance of the Xpert Factor II & Factor V test has not been evaluated with samples from pediatric patients.” Two additional modifications to the test are: (i) an update from “Cepheid GeneXpert® Instrument Systems” to “GeneXpert® Instrument Systems” in the Intended Use Statement, from a branding simplification perspective, and (ii) the creation of a new catalog number (GXFIIFV-US-10) for the modified device that is the subject of this Special 510(k) submission.

The following tables shows the similartities and differences between the Xpert FII& FV test and the predicate device. The differences between Xpert FII & FV and the predicate device do not raise different questions of safety and effectiveness.

Table 1. Similarities between Xpert FII & FV and the Predicate Device

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® FII & FV (Modified)	**Xpert® FII & FV (K223046)**
Regulation	**21 CFR 864.7280** Factor V Leiden DNA Mutation Detection Systems **21 CFR 862.2570** Instrumentation for Clinical Multiplex Test systems	Same
Product Code	**NPR** Test, Factor II G20210A Mutations, Genomic DNA PCR **NPQ** Test, Factor V Leiden Mutations, Genomic DNA PCR **OOI** Real Time Nucleic Acid Amplification System	Same
Device Class	Class II	Same
Indications for Use	Aid in the diagnosis of FII and FV Leiden mutations in individuals with suspected thrombophilia	Same
Technology/ Detection	Fully automated nucleic acid amplification (DNA); real-time PCR	Same
Test Cartridge	Disposable single-use, multi-chambered, fluidic cartridge	Same
Fluidics	Self-contained and automated after specimen is added to the cartridge	Same
Specimen Type	Sodium citrate or EDTA anticoagulated whole blood	Same
Probes	Scorpion® Probes	Same
Internal Controls	• Sample Processing Control (SPC) • Probe Check Control (PCC)	Same
DNA Target Sequence	Sequence specific for Factor II (G20210A) and Factor V Leiden (G1691A) mutations	Same
Time to Result	Approximately 30 minutes to result	Same
Assay Format	Amplification: PCR Detection: Fluorogenic target-specific hybridization	Same

Similarities		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® FII & FV (Modified)	**Xpert® FII & FV (K223046)**
Interpretation of Test Results	Automated (Diagnostic software)	Same
Users	Trained users	Same
Instrument Systems	• GeneXpert Dx Systems • GeneXpert Infinity-48s and Infinity-80 Systems • GeneXpert Systems with Touchscreen	Same
Software	• GeneXpert Dx software version 4.0 or higher • GeneXpert Xpertise software version 6.6 or higher • CEP OS version 2.1 or higher	Same

Table 2. Differences between Xpert FII & FV and the Predicate Device

Differences		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® FII & FV (Modified)	**Xpert® FII & FV (K223046)**
Intended Use	The Xpert® FII & FV test is a qualitative *in vitro* diagnostic genotyping test for the detection of Factor II and Factor V alleles from sodium citrate or EDTA anticoagulated whole blood. Performed on the GeneXpert® Instrument Systems, the test is intended to provide results for Factor II (G20210A) and Factor V Leiden (G1691A) mutations and indicated as an aid in the diagnosis in individuals with suspected thrombophilia.	The Xpert® FII & FV test is a qualitative *in vitro* diagnostic genotyping test for the detection of Factor II and Factor V alleles from sodium citrate or EDTA anticoagulated whole blood. Performed on the **Cepheid** GeneXpert® Instrument Systems, the test is intended to provide results for Factor II (G20210A) and Factor V Leiden (G1691A) mutations and indicated as an aid in the diagnosis in individuals with suspected thrombophilia.
Catalog Number	GXFIIFV-US-10	GXFIFV-10
Instructions for Use - Limitations of the Procedure Section	• The performance of the Xpert Factor II & Factor V test was validated using the procedures provided in this Instructions for Use only. Modifications to these procedures may alter the performance of the test. Results from the Xpert Factor II & Factor V test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.	• The performance of the Xpert Factor II & Factor V test was validated using the procedures provided in this Instructions for Use only. Modifications to these procedures may alter the performance of the test. Results from the Xpert Factor II & Factor V test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

Differences		
Attribute	**Subject Device**	**Predicate Device**
	Xpert® FII & FV (Modified)	**Xpert® FII & FV (K223046)**
	• Rare Factor V mutations (A1696G, G1689A, and A1692C) and any additional SNPs in the probe binding region may interfere with the target detection and yield an INVALID result. • Other rare Factor II mutations in the probe binding region may interfere with the target detection and could yield an INVALID result, or a false HOMOZYGOUS mutant result when occurring concordantly with the Factor II c.*97G>A (G20210A) mutation. • Erroneous test results might occur from improper specimen collection, handling, or storage or sample mix-up. Careful compliance to the instructions in this package is necessary to avoid erroneous results.	• Rare Factor V mutations (A1696G, G1689A, and A1692C) and any additional SNPs in the probe binding region may interfere with the target detection and yield an INVALID result. • Other rare Factor II mutations in the probe binding region may interfere with the target detection and could yield an INVALID result, or a false HOMOZYGOUS mutant result when occurring concordantly with the Factor II c.*97G>A (G20210A) mutation. • **The performance of the Xpert Factor II & Factor V test has not been evaluated with samples from pediatric patients.** • Erroneous test results might occur from improper specimen collection, handling, or storage or sample mix-up. Careful compliance to the instructions in this package is necessary to avoid erroneous results.

5. Summary of Performance Data

No new performance data were provided in this submission. Removal of the erroneous limitation statement – which states that the performance of the test has not been evaluated with samples from pediatric patients - from the Instructions for Use is supported by clinical validation data that was submitted and reviewed as part of the original device clearance (K082118). The change from "Cepheid GeneXpert® Instrument Systems" to "GeneXpert® Instrument Systems" in the intended use statement, and from GXFIIFV-10 to GXFIIFV-US-10 for the catalog number, have no impact on device performance, safety or effectiveness.

6. Conclusion

The intended use of the modified Xpert FII & FV test and the legally marketed predicate device (Xpert FII & FV; K223046) are identical other than a minor update from a branding simplification perspective. The technological characteristics of the modified Xpert FII & FV test are identical to those of the predicate device. The performance of the modified Xpert FII & FV test is acceptable for its intended use and substantially equivalent to the predicate device.