February 15, 2023

Cepheid
Bobbi Ferrell
Principal Regulatory Affairs Specialist
904 Caribbean Drive
Sunnyvale, CA 94089

Re: K223046
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: September 29, 2022
Received: September 29, 2022

Dear Bobbi Ferrell:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 for Hematology Branch
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)*

K223046

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 Cepheid 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.

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5. 510(k) Summary

As required by 21 CFR Section 807.92(c). The purpose of this submission is to submit documentation to support the addition of the GeneXpert Infinity systems for the use with Xpert FII & FV (GXFIIFV-10).

Submitted by:	Cepheid 904 Caribbean Drive Sunnyvale, CA 90489 Phone number: (408) 400-8230 Fax number: (408) 541-6439
Contact:	Bobbi L. Ferrell, MSRA
Date of Preparation:	September 27, 2022
Proprietary/Trade name:	Xpert® FII & FV
Common name:	Xpert® Factor II & Factor V
Type of Test:	Nucleic Acid Amplification Test, DNA, Factor II Prothrombin G20210A and Factor V G1691A (Leiden) qualitative, genotyping
Regulation number, Classification name, Product code:	21 CFR 864.7280, Factor II Prothrombin and Factor V Leiden DNA Mutation Detection Systems, NPQ, NPR 21 CFR 862.2570, Real Time Nucleic Acid Amplification System, OOI;
Classification Advisory Panel	Pathology
Prescription Use	Yes
Predicate Device Test:	Cepheid Xpert HemosIL Factor II & Factor V (K082118)

5.1 Device Description

The Cepheid Xpert® FII & FV is a rapid, automated DNA test for detecting FII and FV 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 instrument platform (comprised of the GeneXpert Dx Systems and GeneXpert Infinity Systems), which performs hands-off real-time, multiplex polymerase chain reaction (PCR) for detection of DNA. In the GeneXpert Instrument Systems platform, sample preparation, amplification, and real-time detection are all fully-automated and completely integrated.

The GeneXpert Instrument Systems have 1 to 80 randomly accessible 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 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 the Factor V gene (at position 1691). The test includes a Sample Processing Control to confirm 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 test is performed on the Cepheid GeneXpert Instrument Systems, which automate and integrate sample purification, nucleic acid amplification and detection of the target sequences in simple or complex samples using real-time PCR. The systems consist of an instrument, personal computer, 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. In this platform, additional sample preparation, amplification, and real-time detection are all fully- automated and completely integrated. The Xpert FII & FV test performed on the GeneXpert Instrument Systems provides results in approximately 30 minutes.

5.2 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 Cepheid 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.

5.3 Technical Characteristics

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

5.4 Substantial Equivalence

The purpose of this Special 510(k) submission is for a modification to an existing device (Xpert® FII & FV) to incorporate its intended use on an additional instrument, the GeneXpert Infinity Systems. Table 5-1 shows the similarities and differences between the Xpert FII & FV test and predicate device. The differences between Xpert FII & FV test and the predicate device do not raise different questions of safety and effectiveness.

Table 5-1: Comparison of Similarities and Differences of Modified and Predicate Xpert FII & FV

Similarities		
Item	**Modified Device**	**Predicate Device**
	Xpert Factor II & Factor V	**Xpert (HemosIL) Factor II & Factor V (K082118)**
Indications for Use	Same	Aid in the identification of individuals suspected with thrombophilia
Sample Preparation	Same	Self-contained and automated after mixed specimen is added to cartridge.
Laboratory Users	Same	Trained users
Specimen Type	Same	Sodium citrate or EDTA anticoagulated whole blood
Test Technology	Same	Fully automated nucleic acid amplification (DNA); real-time PCR
Test Cartridge Technology	Same	Disposable single-use, multi-chambered fluidic cartridge
Internal Controls	Same	Sample processing control (SPC) and probe check control (PCC).
DNA Target Sequence	Same	Sequence specific to for Factor II (G20210A) and Factor V Leiden (G1691A) mutations
Time to Results	Same	Approximately 30 minutes to result
Assay Definition File Results Algorithm	Same	Rules-based algorithms incorporating delta Ct values between targets within a valid Ct range and algorithms based on the Ct value for the targets falling within a valid Ct range.
Differences		
Item	**Modified Device**	**Predicate Device**
	Xpert FII & FV	**Xpert (HemosIL) Factor II & Factor V K082118**
Intended Use (Difference bolded)	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 Cepheid **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.	The Xpert® Factor II & Factor V 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 Cepheid **GeneXpert® Dx 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.
Instrument System	Cepheid GeneXpert Dx Systemsand GeneXpert Infinity-48s and Infinity-80 Systems	Cepheid GeneXpert Dx Systems
Software	GeneXpert Dx software version 4.0 and higher, GeneXpert Infinity-48s and Infinity-80 Xpertise software version 6.6 and higher	GeneXpert Dx software version 2.1 or higher

5.5 Summary of Performance Data

The performance of the Xpert FII & FV test when used with the GeneXpert Infinity Systems was assessed through verification studies, including a Cartridge Hold Time study and Functional Testing study. The assessment of the results from these studies determined that the performance claims of the Xpert FII & FV test were not impacted.

5.6 Conclusion

The results of the verification studies demonstrate that the Xpert FII & FV test as performed on the GeneXpert Infinity Systems is substantially equivalent to the original design of the Xpert (HemosIL) Factor II & Factor V (K082118, the predicate device).