April 27, 2018

Cepheid
Jim Kelly, Ph.D.
Executive Director, Regulatory Affairs
904 Caribbean Drive
Sunnyvale, California 94089

Re: K173840
Trade/Device Name: Xpert CT/NG
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. direct serological test reagents
Regulatory Class: Class II
Product Code: LSL, MKZ, OOI, LIO
Dated: December 15, 2017
Received: December 18, 2017

Dear Jim Kelly:

This letter corrects our substantially equivalent letter of March 16, 2018.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173840

Device Name
Xpert CT/NG

Indications for Use *(Describe)*
The Xpert CT/NG Assay, performed on the GeneXpert Instrument Systems, is a qualitative in vitro real-time PCR test for the automated detection and differentiation of genomic DNA from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) to aid in the diagnosis of chlamydial and gonorrheal urogenital disease. The assay may be used to test the following specimens from asymptomatic and symptomatic individuals: female and male urine, endocervical swab, and patient-collected vaginal swab (collected in a clinical setting).

Ancillary Collection Kits:

Xpert Vaginal/Endocervical Specimen Collection Kit

The Cepheid Xpert Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.

Xpert Urine Specimen Collection Kit

The Cepheid Xpert Urine Specimen Collection Kit is designed to preserve and transport Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis DNA in first-catch female and male urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.

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: (847) 228-3299 Fax number: (847) 890-6589
Contact:	Jim Kelly, Ph.D.
Date Submitted:	February 13, 2017
Device:	
Trade name:	Xpert® CT/NG
Common name:	Xpert CT/NG Assay
Type of Test:	Automated, multiplex real-time polymerase chain reaction (PCR) assay intended for the *in vitro* qualitative detection and differentiation of DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG).
Regulation Number Classification Name:	21 CFR 866.3390 Neisseria spp. direct serological test reagents 21 CFR 866.3120 Chlamydia serological reagents 21 CFR 862.2570 Instrumentation for clinical multiplex systems 21 CFR 866.2900 Microbiological specimen collection and transport device
Regulatory Classification	II
Product code:	LSL: DNA-Reagents, Neisseria MKZ: DNA Probe, Nucleic Acid Amplification, Chlamydia OOI: Real Time Nucleic Acid Amplification System LIO: Device, Specimen Collection
Classification Advisory Panel	Microbiology (83)
Prescription Use	Yes
Predicate Device:	Xpert® CT/NG [510(k) #K121710]

Device Description:

The Xpert CT/NG Assay is a rapid, automated *in vitro* diagnostic test for qualitative detection and differentiation of DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG). The assay is performed on the Cepheid GeneXpert Instrument Systems. The Xpert CT/NG Assay on the GeneXpert Instrument System automates and integrates sample purification, nucleic acid amplification and detection of the target sequences in simple or complex samples using real-time PCR. The system consists of an instrument, personal computer, and preloaded software for running the tests and viewing the results. The system 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.

The Xpert CT/NG Assay includes reagents for the detection and differentiation of CT and NG. A Sample Processing Control (SPC), a Sample Adequacy Control (SAC), and a Probe Check Control (PCC) are also included. The SPC is present to control for adequate processing of the target bacteria and to monitor the presence of inhibitors in the PCR reaction. The SAC reagents detect the presence of a single copy human gene and monitor whether the specimen contains human cells. The PCC verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

The GeneXpert Instrument Systems, comprised of the GeneXpert Dx Systems, the GeneXpert Infinity-48 System and the GeneXpert Infinity-80 System, 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 ancillary specimen collection kits for use with the Xpert CT/NG Assay are the Cepheid® Xpert® Vaginal/Endocervical Specimen Collection kit and the Cepheid® Xpert® Urine Specimen Collection kit.

Device Intended Use:

The Xpert® CT/NG Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* real-time PCR test for the automated detection and differentiation of genomic DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of chlamydial and gonorrheal urogenital disease. The assay may be used to test the following specimens from asymptomatic and symptomatic individuals: female and male urine, endocervical swab, and patient-collected vaginal swab (collected in a clinical setting).

Ancillary Collection Kits:

Xpert Vaginal/Endocervical Specimen Collection Kit

The Cepheid® Xpert® Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.

Xpert Urine Specimen Collection Kit

The Cepheid® Xpert® Urine Specimen Collection Kit is designed to preserve and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in first-catch female and male urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.

Substantial Equivalence:

The Xpert CT/NG Assay is substantially equivalent to the predicate device, Cepheid Xpert CT/NG Assay [510(k) # K121710, cleared on December 27, 2012].

Table 8-1 shows the similarities and differences between the Xpert CT/NG Assay and the predicate device.

Table 8-1: Comparison of Similarities and Differences of the Xpert CT/NG Assay with the Predicate Device

Similarities		
Item	**Device**	**Predicate Device**
	Cepheid Xpert CT/NG Assay	**Cepheid Xpert CT/NG Assay**
510(k) Number	To be assigned	K121710
Regulation	Same	866.3390, 866.3120
Product Code	Same	LSL, MKZ
Device Class	Same	II
Technology/ Detection	Same	Multiplex real-time polymerase chain reaction (PCR)
Intended Use	Same	The Xpert® CT/NG Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* real-time PCR test for the automated

Similarities		
Item	**Device**	**Predicate Device**
	Cepheid Xpert CT/NG Assay	**Cepheid Xpert CT/NG Assay**
		detection and differentiation of genomic DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) to aid in the diagnosis of chlamydial and gonorrheal urogenital disease. The assay may be used to test the following specimens from asymptomatic and symptomatic individuals: female and male urine, endocervical swab, and patient-collected vaginal swab (collected in a clinical setting). Ancillary Collection Kits: The Cepheid® Xpert® Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in endocervical swab specimens (collected by a clinician) and patient-collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay. The Cepheid® Xpert® Urine Specimen Collection Kit is designed to preserve and transport *Chlamydia trachomatis*, *Neisseria*

Similarities		
Item	**Device**	**Predicate Device**
	Cepheid Xpert CT/NG Assay	**Cepheid Xpert CT/NG Assay**
		gonorrhoeae, and *Trichomonas vaginalis* DNA in first-catch female and male urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.
Indication for Use	Same	Asymptomatic and symptomatic patients
Assay Targets	Same	DNA from *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG)
Specimen Type	Same	Urine, endocervical swab, and patient-collected vaginal swab (collected in a clinical setting)
CT Analyte Targets	Same	CT genomic DNA
NG Analyte Targets	Same	NG genomic DNA
Collection Kit	Same	Urine collection kit Swab collection kit
Nucleic Acid Extraction	Yes	Yes
Assay Results	Same	Qualitative
Instrument System	Same	Cepheid GeneXpert Instrument System
Assay Controls	Same	Internal sample processing control (SPC), sample adequacy control (SAC), and probe check control (PCC). External controls available.
Time to obtain test results	Same	Approximately 90 minutes (1.5 hours) to results.

Primary Differences		
	Device	**Predicate Device**
Item	**Cepheid Xpert CT/NG Assay**	**Cepheid Xpert CT/NG Assay**
Limitation	Xpert CT/NG Assay performance has not been evaluated in patients with a history of hysterectomy.	Xpert CT/NG Assay performance has not been evaluated in pregnant women, or in patients with a history of hysterectomy.

The Xpert CT/NG Assay has the same intended use as the predicate device and has the same technological characteristics as the predicate device.

Non-Clinical Studies:

Analytical Sensitivity

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Analytical Reactivity (Inclusivity)

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Analytical Specificity (Exclusivity)

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Interfering Substances

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Carry-Over Contamination Study

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Linearity

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Clinical Performance Characteristics:

Reproducibility and Precision

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information.

Clinical Performance Study

Please refer to the previously FDA-cleared 510(k) #K121710 for additional information. Reanalysis of the clinical data from 510(k) #K121710 was performed for the specimens collected from women who were pregnant at the time of collection.

Conclusions

The intended use and fundamental scientific technology of the Xpert CT/NG Assay is the same as the legally marketed Xpert CT/NG Assay. The reanalysis of the clinical study data from K121710 supports the removal of the limitation statement for the pregnant women. The Xpert CT/NG is substantially equivalent to the predicate device.