DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2017

Roche Molecular Systems, Inc.
David W. Gates, Ph.D.
Sr. Director, Regulatory Affairs
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Re: K163184
Trade/Device Name: cobas® CT/NG v2.0 Test
Regulation Number: 21 CFR 866.3390
Regulation Name: *Neisseria spp.* Direct serological test reagents
Regulatory Class: Class II
Product Code: LSL, MKZ, OOI
Dated: November 11, 2016
Received: November 14, 2016

Dear Dr. Gates:

This letter corrects our substantially equivalent letter of February 9, 2017.

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Steven R. Gitterman -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 January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K163184

Device Name
cobas® CT/NG v2.0 Test

Indications for Use *(Describe)*

The cobas® CT/NG v2.0 Test is an automated, *in vitro* amplification test for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical swab specimens, all collected in cobas® PCR Media (Roche Molecular Systems,, Inc.), and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.

Ancillary Collection Kits

The cobas® PCR Media Dual Swab Sample Kit is used to collect and transport endocervical and vaginal swab specimens. The cobas® PCR Media serves as a nucleic acid stabilizing transport and storage medium for gynecological specimens. Use this collection kit only with the cobas® CT/NG v2.0 Test.

The cobas® PCR Urine Sample Kit is used to collect and transport urine specimens. The cobas® PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens. Use this collection kit only with the cobas® CT/NG v2.0 Test.

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.

cobas® CT/NG v2.0 Test
510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Roche Molecular Systems, Inc.
Address	4300 Hacienda Drive Pleasanton, CA 94588-2722
Contact	David Gates Phone Number: (925) 730-8237 Fax Number: (925) 730-8128 david.gates@roche.com
Date Prepared	November 11, 2016
Proprietary Name	**cobas**® CT/NG v2.0 Test
Proprietary Name: Collection Kits	**cobas**® PCR Media Dual Swab Sample Kit **cobas**® PCR Urine Sample Kit
Common Name	*Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) Test
Common Name: Collection Kits	Specimen Collection Kit
Classification Name	§866.3390 *Neisseria spp.* Direct serological test reagents §866.3120 Chlamydia serological reagents
Product Codes	LSL, MKZ, OOI
Predicate Devices	**cobas®** CT/NG Test (K110923) and **cobas**® CT/NG v2.0 Test (K132270).
Predicate Devices: Collection Kits	**cobas**® PCR Female Swab Sample Kit **cobas**® PCR Urine Sample Kit

1. DEVICE DESCRIPTION

The cobas® CT/NG v2.0 Test is an automated, *in vitro* amplification test for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical swab specimens, all collected in cobas® PCR Media (Roche Molecular Systems,, Inc.), and cervical specimens collected in PreservCyt® solution. The Test comprises of the assay and ancillary collection kits: (a) for female endocervical and vaginal swabs, and (b) for urine.

The changes to the previously cleared **cobas**® CT/NG v2.0 Test are limited to the modification of the original **cobas**® PCR Female Swab Sample Kit (now the **cobas**® PCR Media Dual Swab Sample Kit) to include one flocked endocervical swab and one spun bud swab, instead of two spun bud swabs. All the supporting clinical and analytical performance data, including stability data for specimens stabilized in the **cobas**® PCR Media, may be found under K132270. Additional data was generated, as described in Section 4 below, to demonstrate the substantial equivalence of the modified device to its predicate.

The modified **cobas**® PCR Media Dual Swab Sample Kit is comprised of a collection medium tube and a packet containing two sterile swabs.

Kit Composition:

- cobas® PCR Media Dual Swab Sample Kit (1 spun bud swab and 1 flocked bud swab)
- cobas® PCR Media 1 x 4.3 mL
- ≤40% (w/w) Guanidine hydrochloride Tris-HCl buffer

2. INTENDED USE

The **cobas®** CT/NG v2.0 Test is an automated, *in vitro* amplification test for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical swab specimens, all collected in **cobas®** PCR Media (Roche Molecular Systems,, Inc.), and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.

Ancillary Collection Kits

The **cobas®** PCR Media Dual Swab Sample Kit is used to collect and transport endocervical and vaginal swab specimens. The **cobas®** PCR Media serves as a nucleic acid stabilizing transport and storage medium for gynecological specimens. Use this collection kit only with the **cobas®** CT/NG v2.0 Test.

The **cobas®** PCR Urine Sample Kit is used to collect and transport urine specimens. The **cobas®** PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens. Use this collection kit only with the **cobas®** CT/NG v2.0 Test.

3. TECHNOLOGICAL CHARACTERISTICS

Characteristic	Legally Marketed Predicate Device **cobas**® CT/NG v2.0 Test (K132270)	Submitted Device **cobas**® CT/NG v2.0 Test (K163184)
Intended Use	The **cobas**® CT/NG v2.0 Test is an automated, in vitro nucleic acid amplification test for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical swab specimens, all collected in **cobas**® PCR Media (Roche Molecular Systems, Inc.), and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals. **Ancillary Collection Kits:** The **cobas**® PCR Female Swab Sample Kit is used to collect and transport endocervical and vaginal swab specimens. The **cobas**® PCR Media serves as a nucleic acid stabilizing transport and storage medium for gynecological specimens. Use this collection kit only with the **cobas**® CT/NG v2.0 Test. The **cobas**® PCR Urine Sample Kit is used to collect and transport urine specimens. The **cobas**® PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens. Use this collection kit only with the **cobas**® CT/NG v2.0 Test.	The **cobas**® CT/NG v2.0 Test is an automated, in vitro nucleic acid amplification test for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical swab specimens, all collected in **cobas**® PCR Media (Roche Molecular Systems, Inc.), and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals. **Ancillary Collection Kits:** The **cobas**® PCR Media Dual Swab Sample Kit is used to collect and transport endocervical and vaginal swab specimens. The **cobas**® PCR Media serves as a nucleic acid stabilizing transport and storage medium for gynecological specimens. Use this collection kit only with the **cobas**® CT/NG v2.0 Test. The **cobas**® PCR Urine Sample Kit is used to collect and transport urine specimens. The **cobas**® PCR Media serves as a nucleic acid stabilizing transport and storage medium for urine specimens. Use this collection kit only with the **cobas**® CT/NG v2.0 Test.
Sample Type	Endocervical and vaginal Specimens	Same
PCR Media	≤40% (w/w) Guanidine hydrochloride Tris-HCl buffer	Same
PCR Media Volume	4.3 mL	Same
Swab Number	2	2

Characteristic	Legally Marketed Predicate Device cobas® CT/NG v2.0 Test (K132270)	Submitted Device cobas® CT/NG v2.0 Test (K163184)
Swab Type	2 Spun Bud	1 Spun Bud and 1 Flocked Bud
Sterilization Method	Ethylene Oxide	Same
Bud Size	5.6 mm Diameter	5.6 mm Diameter (Spun) 2.9 mm Diameter (Flocked)
Fiber Composition	Polyester	Same
Shaft Composition	Polystyrene	Same

4. NON-CLINICAL PERFORMANCE EVALUATION

FMEA resulted in the identification of one significant risk for the change to the endocervical swab. To address and mitigate this risk, two studies were conducted:

- Confirmation of equivalent specimen load with the new swab by limiting dilution LoD determination. Limiting dilutions of specimens co-collected with the current, cleared swab and the new flocked swab exhibited consistent drop-out rates at similar levels when tested using the **cobas**® CT/NG v2.0 Test on the **cobas**® 4800 platform. There was no indication that newly proposed flocked swab negatively impacted the analytical sensitivity of the test.
- Correlation study of swab performance between the cleared woven swab and the new flocked swab on the **cobas**® 4800 platform with CT/NG v2.0 with clinical specimens demonstrated a PPA point estimate for CT results of 94.3%, an NPA of 99.7% and an OPA of 99.4%. The 95% confidence interval for NG PPA encompasses 95%. Further statistical analyses of the Ct values for positive concordant results demonstrated that specimens collected with the flocked swab are not significantly different from specimens collected with the woven swab

5. CONCLUSIONS

Conclusions drawn from the nonclinical studies demonstrate that the device is substantially equivalent and performs as well as the legally marketed device identified above.