July 8 2026

Roche Molecular Systems, Inc.
Ginger Emrich
Senior Regulatory Affairs Manager
4300 Hacienda Dr., Pleasanton, CA 94588 USA

Re: K260917
Trade/Device Name: cobas CT/NG for use on the cobas 5800/6800/8800 systems,
cobas TV/MG for use on the cobas 5800/6800/8800 systems
Regulation Number: 21 CFR 866.3393
Regulation Name: Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections
Regulatory Class: Class II
Product Code: QEP
Dated: March 19, 2026
Received: March 19, 2026

Dear Ginger Emrich:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production and process controls (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

UWE SCHERF -S

Uwe Scherf, M.Sc., Ph.D.
Director
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)*
K260917

Device Name
cobas CT/NG for use on the cobas® 5800/6800/8800 systems

Indications for Use *(Describe)*
cobas® CT/NG for use on the cobas® 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in male and female urine, clinician-instructed self-collected vaginal swab specimens (collected in a clinical setting), and clinician-collected vaginal swab specimens, endocervical swab specimens, oropharyngeal (throat) swab specimens and anorectal 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K260917

Device Name
cobas TV/MG for use on the cobas® 5800/6800/8800 systems

Indications for Use *(Describe)*
cobas® TV/MG for use on the cobas® 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Trichomonas vaginalis (TV) and Mycoplasma genitalium (MG) DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens, all collected in cobas® PCR Media (Roche Molecular Systems, Inc.). cobas® TV/MG also detects TV DNA in cervical specimens collected in PreservCyt solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. This test is intended as an aid in the diagnosis of TV and MG infections in individuals suspected to have TV or MG infection.
A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher sensitivity compared to endocervical swabs and urine. For males, urine is the preferred specimen type due to higher sensitivity compared to meatal swabs. If vaginal swab or male urine is not used and MG testing is negative, further testing with the preferred specimen type may be indicated if M. genitalium infection is strongly suspected.

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 for use on the **cobas**® 5800/6800/8800 systems

510(k) Summary

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

Submitter Name	Roche Molecular Systems, Inc.
Address	4300 Hacienda Dr Pleasanton, CA 94588 USA
Contact	Ginger Emrich Email: ginger.emrich@roche.com
Date Prepared	April 15, 2026
Proprietary Name	**cobas**® CT/NG for use on the **cobas**® 5800/6800/8800 systems
Classification Number/Name	21 CFR 866.3393 Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections
Classification Product Code	QEP
Subsequent Product Codes	LSL, MKZ, OOI
Predicate Device	**cobas**® CT/NG for use on the **cobas**® 5800/6800/8800 systems (K202408)

DEVICE DESCRIPTION SUMMARY

cobas® CT/NG for use on the **cobas®** 5800/6800/8800 systems is a qualitative test that enables the detection of CT/NG DNA in endocervical, vaginal, oropharyngeal, anorectal, urine and cervical specimens of infected female patients and oropharyngeal, anorectal and urine specimens in infected male patients. Target specific primers and two probes are used to detect but not discriminate between the CT cryptic plasmid and the ompA gene. Additionally, target-specific primers and two probes are used to detect but not discriminate between two conserved sequences in the NG DR-9 region. The DNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing. In addition, the test utilizes a low titer positive and a negative control.

INTENDED USE

cobas® CT/NG for use on the **cobas®** 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in male and female urine, clinician-instructed self-collected vaginal swab specimens (collected in a clinical setting), and clinician-collected vaginal swab specimens, endocervical swab specimens, oropharyngeal (throat) swab specimens and anorectal 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.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the **cobas®** CT/NG (K260917) and the **cobas®** CT/NG (K202408) is summarized in Table 1 below.

Table 1: Similarities / Differences Between Predicate and Candidate Device

	Predicate Device: cobas® CT/NG (K202408)	**Candidate Device: cobas® CT/NG (K260917)**
Classification Number	21 CFR 866.3393	Same
Classification Name	Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections	Same
Regulatory Class	Class II	Same
Classification Product Code	QEP	Same
Subsequent Product Codes	LSL, MKZ, OOI	Same
Intended Use	**cobas®** CT/NG for use on the **cobas®** 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test, that utilizes real-time polymerase chain reaction (PCR), for the direct detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) DNA in male and female urine, clinician-instructed self-collected vaginal swab specimens (collected in a clinical setting), and clinician-collected vaginal swab specimens, endocervical swab specimens, oropharyngeal (throat) swab specimens and anorectal 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.	Same
Sample Types	• Male and female urine, • vaginal swab specimens, • Endocervical swab specimens, • Oropharyngeal (throat) swab specimens, • Anorectal swab specimens, • Cervical specimens in PreservCyt® Solution	Same
Subject Status	Symptomatic and asymptomatic	Same
Analyte Targets	CT cryptic plasmid DNA CT ompA gene NG genomic DNA	same

	Predicate Device: **cobas® CT/NG (K202408)**	**Candidate Device:** **cobas® CT/NG (K260917)**
Sample Preparation	Automated	Same
Amplification Technology	Real Time PCR	Same
Detection Chemistry	Paired reporter and quencher fluorescence labeled probes (TaqMan Technology) using fluorescence resonance energy transfer (FRET)	Same
Controls used	**cobas®** CT/NG Positive Control Kit **cobas®** Buffer Negative Control Kit	Same
Result Analysis	PCR Cycle threshold analysis	Same
Collection Devices	**cobas®** PCR Urine Sample Kit **cobas®** PCR Media Uni Swab Sample Kit **cobas®** PCR Media Dual Swab Sample Kit ThinPrep Pap Test Physician's Kits.	Same as predicate with the addition of Colli-Pee™•Dx Urine Collection Kit.

NON-CLINICAL PERFORMANCE CHARACTERISTICS

See K173887, K202408 and K254121 for non-clinical/analytical performance information.

CLINICAL PERFORMANCE CHARACTERISTICS

See K173887, K202408 and K254121 for clinical performance information.

CONCLUSIONS

The information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence to the **cobas®** CT/NG for use on the **cobas®** 5800/6800/8000 systems.

cobas® TV/MG for use on the **cobas®** 5800/6800/8800 systems

510(k) Summary

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

Submitter Name	Roche Molecular Systems, Inc.
Address	4300 Hacienda Dr Pleasanton, CA 94588 USA
Contact	Ginger Emrich Email: ginger.emrich@roche.com
Date Prepared	April 15, 2026
Proprietary Name	**cobas®** TV/MG for use on the **cobas®** 5800/6800/8800 Systems
Classification Number/Name	21 CFR 866.3393 Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections
Classification Product Code	QEP
Predicate Device	**cobas®** TV/MG for use on the **cobas®** 5800/6800/8800 Systems (K190433)

DEVICE DESCRIPTION SUMMARY

cobas® TV/MG for use on the **cobas**® 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test for the direct detection of *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens collected in **cobas**® PCR Media (Roche Molecular Systems, Inc.). **cobas**® TV/MG also detects TV DNA in cervical specimens collected in PreservCyt® Solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. The DNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing. In addition, the test utilizes external controls (low titer positive control and a negative control).

INTENDED USE

cobas® TV/MG for use on the **cobas**® 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens, all collected in **cobas**® PCR Media (Roche Molecular Systems, Inc.). **cobas**® TV/MG also detects TV DNA in cervical specimens collected in PreservCyt® solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. This test is intended as an aid in the diagnosis of TV and MG infections in individuals suspected to have TV or MG infection.

A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher sensitivity compared to endocervical swabs and urine. For males, urine is the preferred specimen type due to higher sensitivity compared to meatal swabs. If vaginal swab or male urine is not used and MG testing is negative, further testing with the preferred specimen type may be indicated if *M. genitalium* infection is strongly suspected.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the **cobas**® TV/MG (K260917) and the **cobas**® TV/MG (K190433) is summarized in Table 1 below.

Table 1: Similarities / Differences Between Predicate and Candidate Device

	Predicate Device: cobas® TV/MG (K190433)	**Candidate Device: cobas® TV/MG (K260917)**
Classification Number	21 CFR 866.3393	Same
Classification Name	Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections	Same
Regulatory Class	Class II	Same
Classification Product Code	QEP	Same
Intended Use	**cobas®** TV/MG for use on the **cobas®** 5800/6800/8800 systems is an automated, qualitative in vitro nucleic acid diagnostic test that utilizes real-time polymerase chain reaction (PCR), for the direct detection of *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) DNA in male or female urine, self-collected vaginal swab specimens (collected in a clinical setting), clinician-collected vaginal swab specimens, and endocervical specimens, all collected in **cobas®** PCR Media (Roche Molecular Systems, Inc.). **cobas®** TV/MG also detects TV DNA in cervical specimens collected in PreservCyt® solution and MG DNA in self-collected meatal swab specimens (collected in a clinical setting) and clinician-collected meatal swab specimens. This test is intended as an aid in the diagnosis of TV and MG infections in individuals suspected to have TV or MG infection. A vaginal swab (self-collected or clinician-collected) is the preferred specimen type for MG testing in females due to higher sensitivity compared to endocervical swabs and urine. For males, urine is the preferred specimen type due to higher sensitivity compared to meatal swabs. If vaginal swab or male urine is not used and MG testing is negative, further testing with the preferred specimen type may be indicated if *M. genitalium* infection is strongly suspected.	Same
Sample Types	• Male and female urine, • penile meatal swabs for MG, • vaginal swab specimens, • Endocervical swab specimens, • Cervical specimens in PreservCyt® Solution for TV	Same
Subject Status	Symptomatic and asymptomatic	Same

	Predicate Device: **cobas® TV/MG (K190433)**	**Candidate Device:** **cobas® TV/MG (K260917)**
Sample Preparation	Automated	Same
Amplification Technology	Real Time PCR	Same
Detection Chemistry	Paired reporter and quencher fluorescence labeled probes (TaqMan Technology) using fluorescence resonance energy transfer (FRET)	Same
Controls used	**cobas®** TV/MG Positive Control Kit **cobas®** Buffer Negative Control Kit	Same
Result Analysis	PCR Cycle threshold analysis	Same
Collection Devices	**cobas®** PCR Urine Sample Kit **cobas®** PCR Media Uni Swab Sample Kit **cobas®** PCR Media Dual Swab Sample Kit ThinPrep Pap Test Physician's Kits.	Same as predicate with the addition of Colli-Pee™•Dx Urine Collection Kit.

NON-CLINICAL PERFORMANCE CHARACTERISTICS

See K190433 and K254121 for non-clinical/analytical performance information.

CLINICAL PERFORMANCE CHARACTERISTICS

See K190433 and K254121 for clinical performance information.

CONCLUSIONS

The information provided in this 510(k) Premarket Notification supports a determination of substantial equivalence to the **cobas®** TV/MG for use on the **cobas®** 5800/6800/8000 systems.