August 28, 2026

Roche Molecular Systems, Inc.
Gaila Balniene
Senior Regulatory Affairs Manager
4300 Hacienda Drive
Pleasanton, California 94588

Re: K260045

Trade/Device Name:	cobas Cdiff Nucleic acid test for use on the cobas Liat System (07454945190); cobas Cdiff Postive and Negative Control Kit for use on the cobas Liat System (07454970190)
Regulation Number:	21 CFR 866.3130
Regulation Name:	Clostridium Difficile Toxin Gene Amplification Assay
Regulatory Class:	Class II
Product Code:	OZN, OOI
Dated:	July 29, 2026
Received:	July 29, 2026

Dear Gaila Balniene:

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

RIBHI SHAWAR -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief,
General Bacteriology and Antimicrobial Susceptibility Branch
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K260045

Device Name
cobas Cdiff Nucleic acid test for use on the cobas Liat System (07454945190); cobas Cdiff Positive and Negative Control Kit for use on the cobas Liat System (07454970190)

Indications for Use *(Describe)*
The cobas Cdiff Nucleic acid test for use on the cobas Liat System is an automated, qualitative *in vitro* diagnostic test, that uses real-time polymerase chain reaction (PCR), for the detection of the toxin B (*tcdB*) gene of toxigenic *Clostridioides difficile* (*C. difficile*) in unformed (liquid or soft) stool specimens obtained from patients suspected of having *C. difficile* infection (CDI). The cobas Cdiff Nucleic acid test for use on the cobas Liat System is intended for use as an aid in the diagnosis of CDI in humans in conjunction with clinical and epidemiological risk factors.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

cobas® Cdiff Nucleic acid test for use on the **cobas**® **Liat**® System
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 Drive, Pleasanton, CA 94588-2722
Contact	Gaila Balniene Phone: (510) 305-6980 Email: gaila.balniene@roche.com
Date Prepared	August 26, 2026
Proprietary Name	**cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System
Common Name	**cobas**® Cdiff
Classification	21 CFR 866.3130 Clostridium difficile toxin gene amplification assay
Product Codes	OZN OOI
Predicate Devices	**cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System (K212427)
Establishment Registration	Roche Molecular Systems, Inc. (2243471)

1. DEVICE DESCRIPTION

The **cobas**® Cdiff Nucleic Acid Test for use on the **cobas**® Liat® System (**cobas**® Cdiff) is a rapid, automated *in vitro* diagnostic test for qualitative detection and differentiation of *C. difficile* DNA in human stool specimens.

The **cobas**® Liat® system is intended for *in vitro* diagnostic use and is designed to identify and/or measure the presence of genetic material in a biological sample. The system automates all nucleic acid amplification test processes, including reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, amplification, real-time detection, and result interpretation in a rapid manner.

1.1. Target Selection

The **cobas**® Cdiff test detects *tcdB* target-specific and Internal Control (IC)-specific oligonucleotide sequences. Toxin B (or tcdB) is a major toxin that is implicated in *C. difficile* pathogenesis and allows the differentiation between toxigenic and non-toxigenic *C. difficile* strains. Primers and probe oligonucleotide sequences were designed to detect *C. difficile* organisms, as well as internal control specifically.

1.2. Test Principle

The **cobas**® Cdiff test nucleic acid test is an automated, qualitative *in vitro* nucleic acid diagnostic test that utilizes real-time polymerase chain reaction (PCR) for the qualitative detection and differentiation of *C. difficile* DNA in human stool specimens. The **cobas**® Cdiff test is supported by an assay-specific script, a generic Liat® Assay Specific Package (gLASP), CDFA.

The **cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System is a rapid test that fully automates sample preparation, PCR amplification and real-time detection of target DNA sequences on the **cobas**® Liat® analyzer. The **cobas**® Liat® system is comprised of the **cobas**® Liat® analyzer (analyzer) hardware with integrated **cobas**® Liat® system software (analyzer software + Liat® assay specific package) for running tests and analyzing the results, and a single-use disposable **cobas**® Liat® assay tube (assay tube) that contains all of the sample purification and PCR reagents for the sample preparation and PCR processes. The assay tube is assay-specific and consists of a frame and a plastic straw made of polypropylene. The assay-specific reagents are packaged into the assay tube in separate segments, which are separated by frangible

seals. The **cobas**® Cdiff assay tube hosts the sample preparation and PCR processes. The **cobas**® Cdiff assay tube is self-contained, so the risk of cross-contamination between samples is reduced. The **cobas**® Cdiff assay tube contains an Internal Control (*Bacillus thuringiensis israelensis* or Bti) as well. The IC is present to control for adequate processing of the target bacteria through all steps of the assay process and to monitor the presence of inhibitors in the PCR reactions.

The main features of **cobas**® Liat® system are the following: the software for instrument control, data management and processing, guided workflow management, automated sample preparation and real-time PCR amplification and detection, and connectivity to a Laboratory Information system (LIS) or to data management servers (i.e. middleware) utilized in point of care settings.

2. INDICATIONS FOR USE

The **cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System is an automated, qualitative *in vitro* diagnostic test, that uses real-time polymerase chain reaction (PCR), for the detection of the toxin B (*tcdB*) gene of toxigenic *Clostridioides difficile* (*C. difficile*) in unformed (liquid or soft) stool specimens obtained from patients suspected of having *C. difficile* infection (CDI). The **cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System is intended for use as an aid in the diagnosis of CDI in humans in conjunction with clinical and epidemiological risk factors.

3. TECHNOLOGICAL CHARACTERISTICS

The primary technological characteristics of the modified **cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System are substantially equivalent to the previously cleared, legally marketed, predicate device (K212427). The Indications For Use were not changed for the modified device from the predicate device. Table 1 provides a comparison of the modified device to the predicate device, as cleared through K212427.

Table 1: Comparison of the cobas® Cdiff Nucleic Acid Test for use on the cobas® Liat® System and the Predicate Device

Item Name	Submitted Device: cobas® Cdiff Nucleic acid test for use on the cobas® Liat® System	Predicate Device: cobas® Cdiff Nucleic acid test for use on the cobas® Liat® System (K212427)
Intended Use	Same	The **cobas®** Cdiff Nucleic acid test for use on the **cobas®** Liat® System is an automated, qualitative in vitro diagnostic test that uses real-time polymerase chain reaction (PCR) for the detection of the toxin B (tcdB) gene of toxigenic *Clostridioides difficile* (*C. difficile*) in unformed (liquid or soft) stool specimens obtained from patients suspected of having *C. difficile* infection (CDI). The **cobas®** Cdiff Nucleic acid test for use on the **cobas®** Liat® System is intended for use as an aid in the diagnosis of CDI in humans in conjunction with clinical and epidemiological risk factors.
Regulation Number	Same	21 CFR 866.3130
Product Code	Same	OZN, OOI
Sample Type	Same	Unformed soft stool specimens
Amplification Technology	Same	Real-time PCR
Internal Control	Same	Chemically-inactivated gram-positive *Bacillus thuringiensis israelensis* bacterial organism to monitor the full process of **cobas®** Liat® analyzer. Native sequence in the bacteria is used as the Internal Control Target.
Positive Control	Same	Plasmid in buffer
Negative Control	Same	Buffer only
Analyte Targets	Same	Toxin B (tcdB) gene
Sample Collection Devices	Same	**cobas®** PCR Media Swab Sample Kit
Sample Preparation	Same	Magnetic bead-based nucleic acid extraction automated by **cobas®** Liat® analyzer
Time-to-result	Same	~20 minutes
Result Analysis	Same	Based on PCR cycle threshold analysis
Assay Instrument	Same	**cobas®** Liat® analyzer
Software	**cobas®** Liat® analyzer v4.0.0; generic Liat Assay Specific Packages (gLASPs) assay script, CDFA v1.4.0	**cobas®** Liat® analyzer v3.3 (K212427) Assay script CFDA v1.1
User Complexity	Same	Moderate complexity

4. DESCRIPTION OF CHANGE

The updated **cobas**® Cdiff test integrates the assay script, CDFA 1.4.0 generic Liat Assay Package (gLASP), utilizing the Roche Kinetic Algorithm v2.X (KA2), for use on the **cobas**® Liat® analyzer with software (SW) version 4.0.

The assay script within **cobas**® Liat® assay products was standardized across development and commercial portfolios by migrating the calculation package for result determination, currently used by the **cobas**® Cdiff test, from an older legacy algorithm to a state-of-the-art, Roche Kinetic algorithm utilized across Roche platforms. The Result Interpretation Concept (RIC) remains consistent with the logic used in the current on-market script. In addition, with release of software (SW) version 4.0 for the **cobas**® Liat® analyzer, the **cobas**® Cdiff script (CDFA v1.29.0) was refactored from the current structure to the generic Liat® Assay Package (gLASP) architecture for compatibility.

In comparison to the **cobas**® Cdiff Nucleic acid test cleared under K212427, additional features, updates, and bug fixes have been incorporated into the system design. However, these do not change the Indications For Use, alter the technological characteristics, or significantly change the **cobas**® Cdiff Nucleic acid test system from the previously cleared system.

The primary technological characteristics and intended use of **cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System are substantially equivalent to the legally marketed device K212427. The submitted information in this premarket notification supports a substantial equivalence decision.

5. ASSAY PERFORMANCE

To confirm the determination of the substantial equivalence 1) all original verification and validation data were recalculated using the new algorithm and 2) a side-by-side equivalence study was conducted using a contrived sample panel to compare the current on-market assay script (CDFA v1.1.0) with the updated assay script (CDFA v1.4.0). The results of these comparisons verified and confirmed that the updated configuration maintains the performance characteristics and claims of the test as originally established for the currently cleared device. Based on the results of the analytical studies, the test shows acceptable performance, is suitable for its intended purpose, and detects *C. difficile* targets with reasonable safety and effectiveness.

The product performance is considered clinically validated in the intended use setting with clinical and public health benefits of a molecular POC test available to clinicians and patients. Refer to K171770 for the results and conclusions of nonclinical and clinical performance tests. The conclusions of the nonclinical and clinical tests relevant to the **cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System have not changed from the previously cleared submissions.

6. CONCLUSION

Equivalent performance of the modified device and the current commercial device has been demonstrated, and analytical or clinical performance has not changed. The modified device is substantially equivalent to the predicate device (as cleared through K212427).