October 20, 2021

Roche Molecular Systems, Inc.
Kaitlyn Hameister
Senior Regulatory Affairs Specialist I
4300 Hacienda Drive
Pleasanton, California 94588-2722

Re: K212427
Trade/Device Name: cobas Cdiff nucleic acid test for use on the cobas Liat System
Regulation Number: 21 CFR 866.3130
Regulation Name: Clostridium Difficile Toxin Gene Amplification Assay
Regulatory Class: Class II
Product Code: OZN, OOI
Dated: August 3, 2021
Received: August 4, 2021

Dear Kaitlyn Hameister:

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,

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

Device Name

Indications for Use *(Describe)*

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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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	Kaitlyn Hameister Phone: (925) 368-0589 FAX: (925) 225-0207 Email: kaitlyn.hameister@roche.com
Date Prepared	July 29, 2021
Proprietary Name	**cobas**® Cdiff Nucleic acid test for use on the **cobas**® Liat® System
Common Name	*Clostridioides difficile* Test
Classification Name	*Clostridioides difficile* Toxin Gene Amplification Assay Real Time Nucleic Acid Amplification System
Product Codes	OZN OOI
Regulation Number	21 CFR 866.3130
Predicate Devices	**cobas**® Cdiff Nucleic Acid Test for use on the **cobas**® Liat® System
Establishment Registration	Roche Molecular Systems, Inc. Branchburg, NJ Establishment Number: 2243471 Roche Molecular Systems, Inc. Pleasanton, CA Establishment Number: 3004141078

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® is for *in vitro* diagnostic use. The system is designed to identify and/or measure presence of genetic material in a biological sample. The system automates all nucleic acid amplification test (NAAT) 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 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. The same Internal Control as in the predicate assay (*Bacillus thuringiensis israelensis*) is used. Primers and probe oligonucleotide sequences were designed to detect *C. difficile* genus organisms, as well as with organisms commonly found in normal gut flora. All oligonucleotide sequences remain unchanged from the predicate assay.

1.2. Test Principle

The **cobas**® Cdiff test uses silica magnetic particle-based nucleic acid extraction and TaqMan probe-based real-time PCR amplification and detection. The **cobas**® Liat® Analyzer automates and integrates sample purification, nucleic acid amplification and detection of the target sequence in biological samples. Other than adding the sample to the **cobas**® Cdiff assay tube, no reagent preparation or additional steps are required. The **cobas**® Cdiff assay tube that holds all of the sample purification and PCR reagents and hosts the sample preparation and PCR process specific for the Cdiff analyte. The test uses the assay tube as both the sample and reaction vessel. The assay tube comprises flexible tubing containing all required unit dose reagents pre-packed in tube segments, separated by pressure-sensitive seals, in the order of reagent use.

During the testing process, multiple sample processing actuators of the analyzer compress the **cobas**® Cdiff assay tube to selectively release reagents from tube segments, move the sample from one segment to another, and control reaction conditions such as reaction volume, temperature, pressure, and incubation time. Precise control of all these parameters provides optimal conditions for assay reactions, allowing the test to achieve high performance similar to or better than that of currently available molecular assays. The **cobas**® Liat® Analyzer software controls and coordinates these actions to perform all required assay processes, including sample preparation, nucleic acid extraction, target enrichment, inhibitor removal, nucleic acid elution, and real-time PCR. All assay steps are performed within the closed and self-contained **cobas**® Cdiff assay tube, thereby eliminating the potential for cross-contamination between

samples. The collected data are automatically analyzed and the result is displayed in the assay report on the integrated LCD touch screen of the **cobas**® Liat® Analyzer.

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 (*tcd*B) 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 and intended use of **cobas**® Cdiff for use on the **cobas**® Liat® System are substantially equivalent to the legally marketed device. Table 1 provides a comparison of the modified device to the predicate device, as cleared through K171770.

Table 1: Comparison of the cobas® Cdiff Assay for use on the cobas® Liat® System to the Predicate Device

Item Name	Submitted Device: cobas® Cdiff	Predicate Device: K171770 cobas® Cdiff
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.
Conditions for Use	Same	For prescription use
Regulation Number	Same	21 CFR 866.3130
Classification	Same	*Clostridioides difficile* Toxin Gene Amplification Assay Real Time Nucleic Acid Amplification System
Product Code	Same	OZN, OOI
Sample Type	Same	Unformed soft stool specimens
Amplification Technology	Same	Real-time PCR
Detection Technique	Same	Multiplex assay using different reporter dyes for each target
Error Diagnostic System	Same	Yes, monitors and records system parameters for error recover or abort if unrecoverable
Internal Control	Same	A 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

Item Name	Submitted Device: **cobas® Cdiff**	Predicate Device: K171770 **cobas® Cdiff**
Sample Preparation	Same	Magnetic bead-based nucleic acid extraction automated by **cobas®** Liat® Analyzer
Subject Status	Same	Symptomatic
Assay Instrument	Same	**cobas®** Liat® Analyzer
Software	**cobas®** Liat® Analyzer Core Software 3.3* CDFA 1.1	**cobas®** Liat® Analyzer Core Software 3.0 (K171770) CDFA 1.0
Shelf Life Stability Method	Statistical Sampling with Adapted Acceptance Criteria	Small Batch Sampling

* **cobas®** Liat® Analyzer Software 3.3 is currently cleared by FDA as part of K210385.

4. DESCRIPTION OF CHANGE: SHELF LIFE

The modified **cobas®** Cdiff incorporates changes to shelf life (from 12 months to 9 months).

5. DESIGN AND DEVELOPMENT ACTIVITY SUMMARY

Roche Molecular Diagnostics (RMD), Pleasanton, CA designed and developed the **cobas®** Cdiff nucleic acid test for use on the **cobas®** Liat® System, and coordinated stability testing activities related to shelf life verification. These activities included risk management, requirements management, configuration management, verification testing, and regression analysis.

6. ASSAY PERFORMANCE

A new stability study with modified stability testing approach and acceptance criteria has been performed to evaluate and verify the shelf life of the **cobas®** Cdiff assay. The result of this evaluation determined that the overall **cobas®** Cdiff assay performance and claims are substantially equivalent to the currently cleared device, with reagents up to ten (10) months after the date of manufacture, supporting a shelf life claim of 9 months, as supported by stability testing data.

7. 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 K171770.