

K210385 cobas Cdiff nucleic acid test for use on the cobas Liat SystemSep 9, 2021
212 days to decisionK210385 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k210385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Feb 9, 2021
Decision date	Sep 9, 2021
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	Gaila Balniene
510(k) history	49 submissions · 46 cleared · 1993-2025

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