

K212427 cobas Cdiff nucleic acid test for use on the cobas Liat SystemOct 20, 2021
77 days to decisionK212427 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k212427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Aug 4, 2021
Decision date	Oct 20, 2021
Days to decision	77 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	Kaitlyn Hameister
510(k) history	49 submissions · 46 cleared · 1993-2025

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