

K142422 cobas Cdiff TestMay 20, 2015
265 days to decisionK142422 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k142422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Aug 28, 2014
Decision date	May 20, 2015
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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