

K133936 ARTUS C. DIFFICILE QS-RGQ MDX KITApr 4, 2014
102 days to decisionK133936 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k133936/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Dec 23, 2013
Decision date	Apr 4, 2014
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	QIAGEN GmbH
Location	Hilden, DE
Contact	Kimberly Mapp
510(k) history	13 submissions · 13 cleared · 2012-2026

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