

K123355 AMPLIVUE C. DIFFICILE ASSAYDec 13, 2012
43 days to decisionK123355 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k123355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Oct 31, 2012
Decision date	Dec 13, 2012
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corporation
Location	San Diego, CA, US
Contact	Ronald H Lollar
510(k) history	37 submissions · 35 cleared · 2010-2024

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