

**K170491 Solana C. difficile Assay**May 11, 2017  
83 days to decisionK170491 · Product code: **OZN** · Microbiology  
Source: <https://www.510kdatabase.net/k170491/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Feb 17, 2017
Decision date	May 11, 2017
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170491/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026