

**K123998 QUIDEL MOLECULAR DIRECT C. DIFFICILE ASSAY**Mar 8, 2013  
72 days to decisionK123998 · Product code: **OZN** · Microbiology  
Source: <https://www.510kdatabase.net/k123998/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Dec 26, 2012
Decision date	Mar 8, 2013
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quidel Corp.</b>
Location	Washington, DC, US
Contact	Ronald H Lollar
510(k) history	93 submissions · 93 cleared · 1983-2013

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