

**K130470 BD MAX CDIFF ASSAY, BD MAX INSTRUMENT**Apr 2, 2013  
36 days to decisionK130470 · Product code: **OZN** · Microbiology  
Source: <https://www.510kdatabase.net/k130470/>**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 25, 2013
Decision date	Apr 2, 2013
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Geneohm Sciences Canada, Inc. (Bd Diagnostics)</b>
Location	Quebec, CA
Contact	PATRICIA DIONNE
510(k) history	4 submissions · 3 cleared · 2013-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130470/> 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 28, 2026