

K172569 GenePOC CDiffNov 22, 2017
89 days to decisionK172569 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k172569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Aug 25, 2017
Decision date	Nov 22, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genepoc, Inc.
Location	Quebec, CA
Contact	Guy Sevigny
510(k) history	5 submissions · 5 cleared · 2017-2019

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