

K163085 Simplexa C. difficile DirectFeb 14, 2017
103 days to decisionK163085 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k163085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Nov 3, 2016
Decision date	Feb 14, 2017
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary
Other names	Simplexa C. difficile Positive Control Pack

APPLICANT

Company	Focus Diagnostics, Inc.:Dba Diasorin Molecular, LLC
Location	Cypress, CA, US
Contact	Irene M. Guzman
510(k) history	1 submissions · 1 cleared · 2017-2017

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Device record: <https://www.510kdatabase.net/k163085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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