

K232092 Great Basin Toxigenic C. difficile Direct Test (CDF2)Nov 14, 2023
124 days to decisionK232092 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k232092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Jul 13, 2023
Decision date	Nov 14, 2023
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vela Operations USA
Location	Salt Lake City, UT, US
Contact	Larry Rea
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232092/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026