FDA 510(k) Premarket Notification

K232092 Great Basin Toxigenic C. difficile Direct Test (CDF2)

CLEARED

Nov 14, 2023
124 days to decision

K232092 · 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