

K132726 ICEPLEX C. DIFFICILE ASSAY KIT, ICEPLEX SYSTEMNov 29, 2013
91 days to decisionK132726 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k132726/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C. Difficile Toxin Gene Amplification Assay (OZN)
Date received	Aug 30, 2013
Decision date	Nov 29, 2013
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Primeradx
Location	Mansfield, MA, US
Contact	FAYYAZ MEMNON
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132726/> 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 June 7, 2026