

K102242 OSOM C. DIFFICILE TOXIN A/B TESTDec 21, 2010
134 days to decisionK102242 · Product code: **LLH** · Microbiology
Source: <https://www.510kdatabase.net/k102242/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Aug 9, 2010
Decision date	Dec 21, 2010
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Corporation
Location	Cambridge, MA, US
Contact	CAROL C RYERSON
510(k) history	6 submissions · 6 cleared · 2005-2010

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