

K041951 XPECT CLOSTRIDIUM DIFFICILE TOXIN A/BNov 15, 2004
118 days to decisionK041951 · Product code: **LLH** · Microbiology
Source: <https://www.510kdatabase.net/k041951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Jul 20, 2004
Decision date	Nov 15, 2004
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Remel, Inc.
Location	Lenexa, KS, US
Contact	MARY ANN SILVIUS
510(k) history	17 submissions · 17 cleared · 1994-2017

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