

K081920 BD GENE OHM CDIFF ASSAYDec 19, 2008
169 days to decisionK081920 · Product code: **LLH** · Microbiology
Source: <https://www.510kdatabase.net/k081920/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Jul 3, 2008
Decision date	Dec 19, 2008
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Diagnostics (Geneohm Sciences, Inc.)
Location	San Diego, CA, US
Contact	RAYMOND BOULE
510(k) history	2 submissions · 2 cleared · 2008-2009

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