

**K964887 VIDAS C. DIFFICILE TOXIN A II ASSAY**Apr 8, 1997  
123 days to decisionK964887 · Product code: LLH · Microbiology  
Source: <https://www.510kdatabase.net/k964887/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Dec 6, 1996
Decision date	Apr 8, 1997
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomerieux Vitek, Inc.</b>
Location	Hazelwood, MO, US
Contact	TERRY MCGOVERN
510(k) history	49 submissions · 49 cleared · 1992-1998

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