

**K964864 PROSPECT II CLOSTRIDIUM DIFFILLIE TOXIN A
MICROPLATE ASSAY**Feb 4, 1997
62 days to decisionK964864 · Product code: LLH · Microbiology
Source: <https://www.510kdatabase.net/k964864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Dec 4, 1996
Decision date	Feb 4, 1997
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Alexon Biomedical, Inc.
Location	Glen Ellyn, IL, US
Contact	SUSAN TURNER, PH.D.
510(k) history	5 submissions · 5 cleared · 1988-1997

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