

**K933997 PROSPECT ENTAMOEBA HISTOLYTICA MICROPLATE  
ASSAY**Nov 22, 1993  
97 days to decisionK933997 · Product code: **GMD** · Microbiology  
Source: <https://www.510kdatabase.net/k933997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Latex Agglutination, Cryptococcus Neoformans (GMD)
Date received	Aug 17, 1993
Decision date	Nov 22, 1993
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k933997/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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