

**K993732 BVBLUE**May 15, 2000  
193 days to decisionK993732 · Product code: **MXB** · Chemistry  
Source: <https://www.510kdatabase.net/k993732/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Vaginal, Bacterial Sialidase (MXB)
Date received	Nov 4, 1999
Decision date	May 15, 2000
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gryphus Diagnostics, LLC</b>
Location	Rockville, MD, US
Contact	THOMAS M TSAKERIS
510(k) history	2 submissions · 2 cleared · 2000-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993732/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026