

K050755 MODIFICATION TO BVBLUEApr 6, 2005
14 days to decisionK050755 · Product code: **MXB** · Chemistry
Source: <https://www.510kdatabase.net/k050755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Vaginal, Bacterial Sialidase (MXB)
Date received	Mar 23, 2005
Decision date	Apr 6, 2005
Days to decision	14 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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