

**K983399 GIARDIA/CRYPTOSPORIDIUM COMBO RAPID ASSAY**Jan 11, 1999  
105 days to decisionK983399 · Product code: **MHI** · Microbiology  
Source: <https://www.510kdatabase.net/k983399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Giardia Spp. (MHI)
Date received	Sep 28, 1998
Decision date	Jan 11, 1999
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Diagnostics</b>
Location	San Diego, CA, US
Contact	BARBARA PIZZA
510(k) history	5 submissions · 5 cleared · 1996-2005

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