

**K033864 GENZYME OSOM TRICHOMONAS RAPID TEST**Apr 2, 2004  
112 days to decisionK033864 · Product code: **JWZ** · Microbiology  
Source: <https://www.510kdatabase.net/k033864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Trichomonas (JWZ)
Date received	Dec 12, 2003
Decision date	Apr 2, 2004
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corp.</b>
Location	Cambridge, MA, US
Contact	E.V. GOORCHENKO
Website	<a href="http://www.genzyme.com">http://www.genzyme.com</a>
510(k) history	27 submissions · 27 cleared · 1991-2006

Genzyme Corp. was an American biotechnology company headquartered in Cambridge, Massachusetts. The company specialized in diagnostic and surgical medical devices across multiple therapeutic areas. Genzyme received FDA 510(k) clearances from total submissions between 1991 and 2006. The company's cleared devices spanned chemistry devices, microbiology diagnostics, and surgical implants including wound closure systems and bioresorbable barriers. This regulatory track record reflects the company's broad portfolio across diagnostic and surgical specialties. Genzyme was acquire...

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