

**K061508 OSOM INFLUENZA A&B TEST**Jun 12, 2006  
11 days to decisionK061508 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k061508/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Jun 1, 2006
Decision date	Jun 12, 2006
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corp.</b>
Location	Cambridge, MA, US
Contact	FRED D LASKY
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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