

**K092633 OSOM INFLUENZA A&B TEST , MODEL PN190**Sep 25, 2009  
29 days to decisionK092633 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k092633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Aug 27, 2009
Decision date	Sep 25, 2009
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corporation</b>
Location	Cambridge, MA, US
Contact	FIL BUENVIAJE
510(k) history	6 submissions · 6 cleared · 2005-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092633/> 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 20, 2026