

**K132237 PRODESSE PROFAST+ ASSAY**Aug 26, 2013  
39 days to decisionK132237 · Product code: **OQW** · Microbiology  
Source: <https://www.510kdatabase.net/k132237/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	2009 H1n1 Influenza Virus (swine Origin), Nucleic Acid Or Antigen, Detection And Identification (OQW)
Date received	Jul 18, 2013
Decision date	Aug 26, 2013
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gen-Probe Prodesse, Inc.</b>
Location	Waukesha, WI, US
Contact	EMILY ZIEGLER
510(k) history	10 submissions · 10 cleared · 2010-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132237/> 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 8, 2026