

**K110968 PROFLU+ ASSAY**Jun 27, 2011  
82 days to decisionK110968 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k110968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Apr 6, 2011
Decision date	Jun 27, 2011
Days to decision	82 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	KAREN HARRINGTON
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/k110968/> 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