

**K091053 PROPARAFLU+ASSAY**Nov 20, 2009  
221 days to decisionK091053 · Product code: **OOU** · Microbiology  
Source: <https://www.510kdatabase.net/k091053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Parainfluenza Multiplex Nucleic Acid Assay (OOU)
Date received	Apr 13, 2009
Decision date	Nov 20, 2009
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prodesse, Inc.</b>
Location	Waukesha, WI, US
Contact	KAREN HARRINGTON
510(k) history	6 submissions · 6 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091053/> 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 22, 2026