

**K132159 PROADENO+ ASSAY**Aug 14, 2013  
33 days to decisionK132159 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k132159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jul 12, 2013
Decision date	Aug 14, 2013
Days to decision	33 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/k132159/> 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