

**K123838 PRO HMPV+ ASSAY**Jan 16, 2013  
34 days to decisionK123838 · Product code: **OEM** · Microbiology  
Source: <https://www.510kdatabase.net/k123838/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Human Metapneumovirus (hmpv) Rna Assay System (OEM)
Date received	Dec 13, 2012
Decision date	Jan 16, 2013
Days to decision	34 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/k123838/> 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