

**K163628 Idylla Respiratory (IFV-RSV) Panel**Aug 30, 2017  
251 days to decisionK163628 · Product code: **OCC** · Microbiology  
Source: <https://www.510kdatabase.net/k163628/>**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	Dec 22, 2016
Decision date	Aug 30, 2017
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Janssen Pharmaceutica NV</b>
Location	Beerse, BE
Contact	SARAH PARSONS
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163628/> 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 May 31, 2026