

**K162438 Sofia Influenza A+B FIA on Sofia 2**Apr 14, 2017  
226 days to decisionK162438 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k162438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Aug 31, 2016
Decision date	Apr 14, 2017
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quidel Corporation</b>
Location	San Diego, CA, US
Contact	Jennifer S. Rial
510(k) history	37 submissions · 35 cleared · 2010-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162438/> 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 14, 2026