

**K241188 Acucy® Influenza A&B Test with the Acucy® 2 System**Apr 18, 2025  
354 days to decisionK241188 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k241188/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Apr 29, 2024
Decision date	Apr 18, 2025
Days to decision	354 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SEKISUI Diagnostics, LLC</b>
Location	San Diegi, CA, US
Contact	Craig Jolicoeur
Website	<a href="https://www.sekisuidiagnostics.com">https://www.sekisuidiagnostics.com</a>
510(k) history	6 submissions · 6 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241188/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026