

K182001 Acucy Influenza A&B Test with the Acucy System

Dec 17, 2018
144 days to decision

K182001 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k182001/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Jul 26, 2018
Decision date	Dec 17, 2018
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	SEKISUI Diagnostics, LLC
Location	San Diegi, CA, US
Contact	Shelly Harris
Website	https://www.sekisuidiagnostics.com
510(k) history	6 submissions · 6 cleared · 2012-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182001/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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