

K192719 Osom Ultra Plus Flu A&B Test KitApr 3, 2020
190 days to decisionK192719 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k192719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Sep 26, 2019
Decision date	Apr 3, 2020
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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