

K123182 OSOM INFLUENZA A&B TEST MODEL 190Nov 5, 2012
26 days to decisionK123182 · Product code: **GNX** · Microbiology
Source: <https://www.510kdatabase.net/k123182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antigens, Cf (including Cf Control), Influenza Virus A, B, C (GNX)
Date received	Oct 10, 2012
Decision date	Nov 5, 2012
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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