

K253971 Visby Medical Flu and COVID-19 TestMay 27, 2026
167 days to decisionK253971 · Product code: **SIA** · Microbiology
Source: <https://www.510kdatabase.net/k253971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 11, 2025
Decision date	May 27, 2026
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visby Medical, Inc.
Location	San Jose, CA, US
Contact	Jennifer Albrecht
510(k) history	4 submissions · 3 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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