

K242526 Visby Medical Respiratory Health TestFeb 19, 2025
177 days to decisionK242526 · Product code: **QOF** · Microbiology
Source: <https://www.510kdatabase.net/k242526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Multi-target Respiratory Specimen Nucleic Acid Test Including Sars-cov-2 And Other Microbial Agents (QOF)
Date received	Aug 26, 2024
Decision date	Feb 19, 2025
Days to decision	177 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	3 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242526/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026