

K260787 FebriDx Bacterial/Non-bacterial AssayMar 24, 2026
14 days to decisionK260787 · Product code: **QXA** · Microbiology
Source: <https://www.510kdatabase.net/k260787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Lateral Flow Immunochromatography Assay For Host Biomarkers Of Respiratory Infection (QXA)
Date received	Mar 10, 2026
Decision date	Mar 24, 2026
Days to decision	14 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lumos Diagnostics, Inc.
Location	Carlsbad, CA, US
Contact	Susan Hibbeln
510(k) history	2 submissions · 2 cleared · 2023-2026

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