

**K230917 FebriDx Bacterial / Non-bacterial Point of Care Assay**Jun 30, 2023  
88 days to decisionK230917 · Product code: **QXA** · Microbiology  
Source: <https://www.510kdatabase.net/k230917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lateral Flow Immunochromatography Assay For Host Biomarkers Of Respiratory Infection (QXA)
Date received	Apr 3, 2023
Decision date	Jun 30, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**CLINICAL EVIDENCE - NCT02018198****FebriDx DISRUPT Acute Respiratory Infection Trial in Acute Respiratory Infection: An Evaluation of FebriDx® POC Test**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	540 patients (actual)
Study sites	20 sites
Condition studied	Acute Respiratory Tract Infections
Study type	Observational
Completion date	Jun 10, 2021
Sponsor	Rapid Pathogen Screening (Industry)

**Primary outcome**

The primary outcome is the presence of a bacterial associated systemic host immune response or viral associated systemic host immune response related to an acute community acquired febrile acute respiratory tract infection, as compared to final diagnosis

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02018198](https://clinicaltrials.gov/study/NCT02018198)