

K241676 TriVerity

Jan 10, 2025
213 days to decision

K241676 · Product code: **PRE** · Microbiology
Source: <https://www.510kdatabase.net/k241676/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rt-qpcr Assay For Mrna Transcript Immune Biomarkers (PRE)
Date received	Jun 11, 2024
Decision date	Jan 10, 2025
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inflammatix, Inc.
Location	Sunnyvale, CA, US
Contact	Diana Lane
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT03606382

Collection of Clinical Specimens From Volunteers for Assay Development

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	6 patients (actual)
Study sites	1 site
Condition studied	Acute Respiratory Infection
Study type	Observational
Completion date	May 1, 2019
Sponsor	Inflammatix (Industry)

Primary outcome

Collection of Specimens from Volunteers for the Development and Validation of HostDx Tests

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03606382

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k241676/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026