

K251749 Flowflex Plus RSV + Flu A/B + COVID Home TestOct 22, 2025
138 days to decisionK251749 · Product code: **SCA** · Microbiology
Source: <https://www.510kdatabase.net/k251749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	Jun 6, 2025
Decision date	Oct 22, 2025
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	ACON Laboratories, Inc.
Location	San Diego, CA, US
Contact	Catherine Shi
Website	http://www.aconlabs.com/
510(k) history	85 submissions · 85 cleared · 1998-2025

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	James Mullally

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k251749/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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