FDA 510(k) Premarket Notification

CLEARED

K250377 Flowflex Plus COVID-19 + Flu A/B Home Test

May 10, 2025
89 days to decision

K250377 · Product code: **SCA** · Microbiology
Source: https://www.510kdatabase.net/k250377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	Feb 10, 2025
Decision date	May 10, 2025
Days to decision	89 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