

K230828 Flowflex COVID-19 Antigen Home TestNov 9, 2023
227 days to decisionK230828 · Product code: **QYT** · Microbiology
Source: <https://www.510kdatabase.net/k230828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Mar 27, 2023
Decision date	Nov 9, 2023
Days to decision	227 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	Qiyi Xie
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, LLC
Contact	James E 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/k230828/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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