

**K251697 Flowflex® Plus Strep A Rapid Test Cassette**Nov 26, 2025  
177 days to decisionK251697 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k251697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jun 2, 2025
Decision date	Nov 26, 2025
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Flowflex® Plus Strep A Rapid Test Strip

**APPLICANT**

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Company	<b>ACON Laboratories, Inc.</b>
Location	San Diego, CA, US
Contact	Catherine Shi
Website	<a href="http://www.aconlabs.com/">http://www.aconlabs.com/</a>
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**

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Consulting firm	<b>MCRA</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k251697/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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