

**K261212 Flowflex Plus RSV + Flu A/B + COVID Rapid Test**Jul 10, 2026  
87 days to decisionK261212 · Product code: **SCA** · Microbiology  
Source: <https://www.510kdatabase.net/k261212/>**SUBMISSION DETAILS**

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|                       |                                                              |
|-----------------------|--------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Dual Track                                                   |
| Device classification | Multi-analyte Respiratory Virus Antigen Detection Test (SCA) |
| Date received         | Apr 14, 2026                                                 |
| Decision date         | Jul 10, 2026                                                 |
| Days to decision      | 87 days                                                      |
| Third-party review    | No                                                           |
| Combination product   | No                                                           |
| PCCP authorized       | No                                                           |
| Summary / Statement   | Statement                                                    |

**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 | 86 submissions · 86 cleared · 1998-2026                         |

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 ...