

# K151595 On Call Express Pro Blood Glucose Monitoring System

Sep 5, 2015  
85 days to decisionK151595 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k151595/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received         | Jun 12, 2015  |
| Decision date         | Sep 5, 2015   |
| Days to decision      | 85 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>ACON Laboratories, Inc.</b>                                  |
| Location       | San Diego, CA, US   |
| Contact        | Qiyi Xie  |
| 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 ...