

K101371 ON CALL PLUS DIABETES MONITORING SOFTWAREJan 7, 2011
235 days to decisionK101371 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k101371/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received | May 17, 2010 |
| Decision date | Jan 7, 2011 |
| Days to decision | 235 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | ACON Laboratories, Inc. |
| Location | San Diego, CA, US |
| Contact | RICHARD LENART |
| 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 ...
