

**K122110 ACON ON CALL VIVID PAL BLOOD GLUCOSE MONITORING SYSTEM**Nov 21, 2012  
127 days to decisionK122110 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k122110/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jul 17, 2012
Decision date	Nov 21, 2012
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

**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 ...