

K163271 i-Stat Alinity System with i-Stat Glucose testApr 10, 2017
140 days to decisionK163271 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k163271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Nov 21, 2016
Decision date	Apr 10, 2017
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Point of Care, Inc.
Location	Princeton, NJ, US
Contact	Maria L Figueroa
510(k) history	19 submissions · 19 cleared · 2011-2025

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