

K223755 i-STAT G cartridge with the i-STAT 1 SystemSep 11, 2023
270 days to decisionK223755 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k223755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 15, 2022
Decision date	Sep 11, 2023
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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