

K223710 i-STAT CG8+ cartridge with the i-STAT 1 SystemJul 28, 2023
228 days to decisionK223710 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k223710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 12, 2022
Decision date	Jul 28, 2023
Days to decision	228 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	Jacquelyn Gesumaria
510(k) history	19 submissions · 19 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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