

K210958 i-STAT CHEM8+ cartridge with the i-STAT 1 SystemAug 13, 2021
135 days to decisionK210958 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k210958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Mar 31, 2021
Decision date	Aug 13, 2021
Days to decision	135 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	Maria Figueroa
510(k) history	19 submissions · 19 cleared · 2011-2025

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