

K183678 i-STAT CHEM8+ cartridge with the i-STAT 1 SystemFeb 7, 2020
406 days to decisionK183678 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k183678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 28, 2018
Decision date	Feb 7, 2020
Days to decision	406 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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