

K261039 i-STAT Crea cartridge with the i-STAT 1 SystemJun 26, 2026
88 days to decisionK261039 · Product code: **CGL** · Chemistry
Source: <https://www.510kdatabase.net/k261039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Based, Enzymatic, Creatinine (CGL)
Date received	Mar 30, 2026
Decision date	Jun 26, 2026
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Point of Care, Inc.
Location	Princeton, NJ, US
Contact	Brian Ma
510(k) history	21 submissions · 21 cleared · 2011-2026

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