

**K191360 i-STAT CHEM8+ cartridge with the i-STAT 1 System**Feb 14, 2020  
269 days to decisionK191360 · Product code: **JFP** · Chemistry  
Source: <https://www.510kdatabase.net/k191360/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Calcium (JFP)
Date received	May 21, 2019
Decision date	Feb 14, 2020
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191360/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026