

K183680 i-STAT CHEM8+ cartridge with the i-STAT 1 SystemFeb 28, 2020
427 days to decisionK183680 · Product code: **JPI** · Hematology
Source: <https://www.510kdatabase.net/k183680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Hematocrit Measuring (JPI)
Date received	Dec 28, 2018
Decision date	Feb 28, 2020
Days to decision	427 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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