

**K163078 DC-UIBC-CAL**Dec 8, 2016  
35 days to decisionK163078 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k163078/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 3, 2016
Decision date	Dec 8, 2016
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sekisui Diagnostics P.E.I., Inc.</b>
Location	Prince Edward Island, CA
Contact	PENNY WHITE
510(k) history	6 submissions · 6 cleared · 2011-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163078/> 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 27, 2026