

**K130915 XL-200 CLINICAL CHEMISTRY ANALYZER, JAS  
GLUCOSE REAGENT, ISE REAGENT PACK**

May 15, 2014  
408 days to decision

K130915 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k130915/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	Apr 2, 2013
Decision date	May 15, 2014
Days to decision	408 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jas Diagnostics, Inc.</b>
Location	Miami, FL, US
Contact	DAVID H JOHNSTON
510(k) history	20 submissions · 20 cleared · 2000-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k130915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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