

**K143324 IDS-iSYS CTX-I Calibration Verifiers**Mar 30, 2015  
131 days to decisionK143324 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k143324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 19, 2014
Decision date	Mar 30, 2015
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunodiagnostic Systems , Ltd.</b>
Location	Tyne And Wear, GB
Contact	ROMA YOUNG
510(k) history	23 submissions · 23 cleared · 1994-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143324/> 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 June 4, 2026