

**K110412 IDS-ISYS IFG-I CONTROL SET**Mar 16, 2011  
30 days to decisionK110412 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k110412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Feb 14, 2011
Decision date	Mar 16, 2011
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Immunodiagnostic Systems , Ltd.</b>
Location	Tyne And Wear, GB
Contact	MICK FENTON
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/k110412/> 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 19, 2026