

**K161082 IDS-iSYS 17-OH Progesterone Control Set, IDS-iSYS  
17-OH Progesterone Calibration Verifiers**May 17, 2016  
29 days to decisionK161082 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k161082/>**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	Apr 18, 2016
Decision date	May 17, 2016
Days to decision	29 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	MICK HENDERSON
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/k161082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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