

**K172257 TrueDX hCG Early Result Pregnancy Test (Midstream Format), TrueDX hCG Early Result Pregnancy Test (Cassette Format), VeriClear Early Result Pregnancy Test (Midstream Format), VeriClear Early Result Pregnancy Test (Cassette Format)**

Dec 22, 2017  
149 days to decision

K172257 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k172257/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 26, 2017
Decision date	Dec 22, 2017
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>True Diagnostics, Inc.</b>
Location	Carlsbad, CA, US
Contact	Jerry Lee
510(k) history	2 submissions · 2 cleared · 2017-2019

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

Device record: <https://www.510kdatabase.net/k172257/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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