

**K152013 QUANTA Flash dsDNA, QUANTA Flash dsDNA  
Calibrators and QUANTA Flash dsDNA Controls**Apr 11, 2016  
265 days to decisionK152013 · Product code: **LSW** · Immunology  
Source: <https://www.510kdatabase.net/k152013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody, Antigen And Control (LSW)
Date received	Jul 21, 2015
Decision date	Apr 11, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inova Diagnostics, Inc.</b>
Location	San Diego, CA, US
Contact	Gabriella Lakos
Website	<a href="https://www.inovadx.com">https://www.inovadx.com</a>
510(k) history	138 submissions · 136 cleared · 1988-2026

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...

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

Device record: <https://www.510kdatabase.net/k152013/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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