

**K113863 QUANTA FLASH DGP IGA, QUANTA FLASH DGP IGG,  
QUANTA FLASH DGP IGA CALIBRATORS, QUANTA FLASH  
DGP IGG CALIBRATORS**

Sep 20, 2012  
265 days to decision

K113863 · Product code: **MST** · Immunology  
Source: <https://www.510kdatabase.net/k113863/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Dec 30, 2011
Decision date	Sep 20, 2012
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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...