

K141274 QUANTA FLASH ¿2GP1-DOMAIN1Feb 13, 2015
273 days to decisionK141274 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k141274/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV) |
| Date received | May 16, 2014 |
| Decision date | Feb 13, 2015 |
| Days to decision | 273 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | CONTROLS, HEMOSIL ACUSTAR ANTI-¿2GPI DOMAIN1; CONTROLS. |

APPLICANT

| | |
|----------------|---|
| Company | Inova Diagnostics, Inc. |
| Location | San Diego, CA, US |
| Contact | Roger Albesa |
| Website | https://www.inovadx.com |
| 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...