

K122923 QUANTA FLASH ENA7May 7, 2013
225 days to decisionK122923 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k122923/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Extractable Antinuclear Antibody, Antigen And Control (LLL) |
| Date received | Sep 24, 2012 |
| Decision date | May 7, 2013 |
| Days to decision | 225 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Inova Diagnostics, Inc. |
| Location | San Diego, CA, US |
| Contact | MICHAEL MAHLER |
| 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...
