FDA 510(k) Premarket Notification

CLEARED

K120817 QUANTA FLASH ACL LGA, QUANTA FLASH B2GP1 IGA

Feb 26, 2013
344 days to decision

K120817 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k120817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Mar 19, 2012
Decision date	Feb 26, 2013
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Inova Diagnostics, Inc.**
Location	San Diego, CA, US
Contact	ROSANNA KEIVENS
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...