

**K123593 QUANTA FLASH SM, QUANTA FLASH RNP, QUANTA
FLASH SM CALIBRATORS, QUANTA FLASH RNP
CALIBRATORS, QUANTA FLASH SM CONTROLS,**Apr 17, 2013
147 days to decisionK123593 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k123593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Nov 21, 2012
Decision date	Apr 17, 2013
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inova Diagnostics, Inc.
Location	San Diego, CA, US
Contact	GABRIELLA LAKOS
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...