FDA 510(k) Premarket Notification

K123880 QUANTA FLASH CENTROMERE

CLEARED

Feb 7, 2014
417 days to decision

K123880 · Product code: **LJM** · Immunology
Source: https://www.510kdatabase.net/k123880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Dec 17, 2012
Decision date	Feb 7, 2014
Days to decision	417 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Inova Diagnostics, Inc.**
Location	San Diego, CA, US
Contact	ANDREA SEAMAN
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...