FDA 510(k) Premarket Notification

K946385 QUANTA LITE ACA IGM (HRP)

CLEARED

Jul 18, 1995
221 days to decision

K946385 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k946385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Dec 9, 1994
Decision date	Jul 18, 1995
Days to decision	221 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Inova Diagnostics, Inc.**
Location	San Diego, CA, US
Contact	BYRS C MYERS
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...