FDA 510(k) Premarket Notification

K984222 QUANTA LITE LYME IGG ELISA

CLEARED

Apr 15, 1999
141 days to decision

K984222 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k984222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 25, 1998
Decision date	Apr 15, 1999
Days to decision	141 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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