FDA 510(k) Premarket Notification

CLEARED

K981328 QUANTA LITE PR3 IGG (SERINE PROTEASE) TEST KIT

Jun 19, 1998
67 days to decision

K981328 · Product code: **MOB** · Immunology
Source: https://www.510kdatabase.net/k981328/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Apr 13, 1998
Decision date	Jun 19, 1998
Days to decision	67 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...