

K021482 QUANTA LITE SLA (SOLUBLE LIVER ANTIGEN) ELISAJul 30, 2002
83 days to decisionK021482 · Product code: **NIY** · Immunology
Source: <https://www.510kdatabase.net/k021482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Anti-soluble Liver Antigen (sla), Autoimmune Hepatitis (NIY)
Date received	May 8, 2002
Decision date	Jul 30, 2002
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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