

K011140 QUANTA PLEX ENA PROFILE 4Jul 27, 2001
105 days to decisionK011140 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k011140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Apr 13, 2001
Decision date	Jul 27, 2001
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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