

K901595 NOVA LITE(TM) ANA MK

Apr 26, 1990
21 days to decision

K901595 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k901595/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Apr 5, 1990
Decision date	Apr 26, 1990
Days to decision	21 days
Third-party review	No

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...
