

K000535 QUANTA LITE LKM-1 ELISAJun 7, 2000
111 days to decisionK000535 · Product code: **NBS** · Immunology
Source: <https://www.510kdatabase.net/k000535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Lkm-1 (liver/kidney Microsome, Type 1) (NBS)
Date received	Feb 17, 2000
Decision date	Jun 7, 2000
Days to decision	111 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Inova Diagnostics, Inc.
Location	San Diego, CA, US
Contact	GARY L NORMAN
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...
