FDA 510(k) Premarket Notification

K955022 QUANTA LITE MPO

CLEARED

Mar 19, 1996
138 days to decision

K955022 · Product code: **MOB** · Immunology
Source: https://www.510kdatabase.net/k955022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Nov 2, 1995
Decision date	Mar 19, 1996
Days to decision	138 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k955022/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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