FDA 510(k) Premarket Notification

CLEARED

K163525 QUANTA Flash M2 (MIT3), QUANTA Flash M2 (MIT3) Calibrators, QUANTA Flash M2 (MIT3) Controls

Sep 5, 2017
264 days to decision

K163525 · Product code: **DBM** · Immunology
Source: https://www.510kdatabase.net/k163525/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Dec 15, 2016
Decision date	Sep 5, 2017
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Inova Diagnostics, Inc.**
Location	San Diego, CA, US
Contact	Peter Martis
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/k163525/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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