

**K933180 QUANTA LITE MITOCHONDRIA M2 ELISA**Aug 5, 1993  
36 days to decisionK933180 · Product code: **DGC** · Immunology  
Source: <https://www.510kdatabase.net/k933180/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Jun 30, 1993
Decision date	Aug 5, 1993
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Inova Diagnostics, Inc.</b>
Location	San Diego, CA, US
Contact	BRYN MYERS
Website	<a href="https://www.inovadx.com">https://www.inovadx.com</a>
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...

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