

**K971335 QUANTA LITE CMV IGG ELISA**Dec 1, 1997  
235 days to decisionK971335 · Product code: **LFZ** · Microbiology  
Source: <https://www.510kdatabase.net/k971335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Apr 10, 1997
Decision date	Dec 1, 1997
Days to decision	235 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	BRYC 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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