

**K875361 SERODOT CMV (CYTOMEGALOVIRUS) IGG TEST KIT**May 13, 1988  
134 days to decisionK875361 · Product code: **LFZ** · Microbiology  
Source: <https://www.510kdatabase.net/k875361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Dec 31, 1987
Decision date	May 13, 1988
Days to decision	134 days
Third-party review	No

**APPLICANT**

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Company	<b>Disease Detection International, Inc.</b>
Location	Irvine, CA, US
Contact	EL-BADRY
510(k) history	20 submissions · 20 cleared · 1988-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k875361/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026