

**K981163 DIAMEDIX IS-CMV IGG TEST SYSTEM**Sep 21, 1998  
174 days to decisionK981163 · Product code: **LFZ** · Microbiology  
Source: <https://www.510kdatabase.net/k981163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Mar 31, 1998
Decision date	Sep 21, 1998
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diamedix Corp.</b>
Location	Miami, FL, US
Contact	LYNNE STIRLING
510(k) history	68 submissions · 68 cleared · 1986-2011

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