

**K891393 ORGENICS IMMUNOCOMB(TM) CMV IGG ANTIBODY
TEST KIT**Jun 23, 1989
101 days to decisionK891393 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k891393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Mar 14, 1989
Decision date	Jun 23, 1989
Days to decision	101 days
Third-party review	No

APPLICANT

Company	Orgenics, Ltd.
Location	Washington, DC, US
Contact	BRUCE F MACKLER
510(k) history	3 submissions · 3 cleared · 1989-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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