

**K203612 Capture-CMV**Mar 22, 2021  
102 days to decisionK203612 · Product code: **LJO** · Microbiology  
Source: <https://www.510kdatabase.net/k203612/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Iha, Cytomegalovirus (LJO)
Date received	Dec 10, 2020
Decision date	Mar 22, 2021
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immucor, Inc.</b>
Location	Norcross, GA, US
Contact	Steven Appel
510(k) history	3 submissions · 3 cleared · 1991-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203612/> 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 May 27, 2026