

**K100433 IMMULITE 2000 CMV IGM, IMMULITE CMV IGM CONTROLS, AND IMMULITE 200 CMV IGM ADJUSTOR MODEL L2KCM2, L2KCM6, LCMC1, LCMC2,**May 13, 2010  
86 days to decisionK100433 · Product code: **LKQ** · Microbiology  
Source: <https://www.510kdatabase.net/k100433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm,if, Cytomegalovirus Virus (LKQ)
Date received	Feb 16, 2010
Decision date	May 13, 2010
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	ROBERT C EUSEBIO
510(k) history	92 submissions · 92 cleared · 2008-2025

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