

K012311 IMMULITE 2000 GENTAMICIN, MODELS L2KGE2 (200 TESTS), L2KGE6 (600 TESTS)Aug 20, 2001
28 days to decisionK012311 · Product code: LCD · Chemistry
Source: <https://www.510kdatabase.net/k012311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Jul 23, 2001
Decision date	Aug 20, 2001
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

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