

K991597 COBAS INTEGRA AMIKACIN MABJul 22, 1999
73 days to decisionK991597 · Product code: **LGJ** · Toxicology
Source: <https://www.510kdatabase.net/k991597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Amibacin (LGJ)
Date received	May 10, 1999
Decision date	Jul 22, 1999
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	LISA GERARD
510(k) history	264 submissions · 263 cleared · 1999-2013

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