

**K945523 COBAS(R)-FP REAGENTS FOR GENTAMICIN AND  
COBAS(R)-FP GENTAMICIN CALIBRATORS**Mar 9, 1995  
119 days to decisionK945523 · Product code: **LCQ** · Toxicology  
Source: <https://www.510kdatabase.net/k945523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay Gentamicin (LCQ)
Date received	Nov 10, 1994
Decision date	Mar 9, 1995
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	CAROL L KRIEGER
510(k) history	296 submissions · 296 cleared · 1983-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945523/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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