

**K964670 ROCHE COBAS-FP REAGENTS FOR TOBRAMYCIN**Feb 4, 1997  
75 days to decisionK964670 · Product code: **LFW** · Toxicology  
Source: <https://www.510kdatabase.net/k964670/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Tobramycin (LFW)
Date received	Nov 21, 1996
Decision date	Feb 4, 1997
Days to decision	75 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	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

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