

**K944371 TOBRAMYCIN FPIA REAGENT SET AND CALIBRATOR**Nov 10, 1994  
64 days to decisionK944371 · Product code: **LFW** · Chemistry  
Source: <https://www.510kdatabase.net/k944371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Tobramycin (LFW)
Date received	Sep 7, 1994
Decision date	Nov 10, 1994
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	HOYLE D HILL
510(k) history	164 submissions · 164 cleared · 1984-2002

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