

**K943550 GENTAMICIN FPIA REAGENT SET AND CALIBRATORS**Nov 17, 1994  
119 days to decisionK943550 · Product code: **LCQ** · Toxicology  
Source: <https://www.510kdatabase.net/k943550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay Gentamicin (LCQ)
Date received	Jul 21, 1994
Decision date	Nov 17, 1994
Days to decision	119 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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