

**K940376 QMS GENTAMICIN ASSAY**Jun 2, 1994  
127 days to decisionK940376 · Product code: **LCD** · Toxicology  
Source: <https://www.510kdatabase.net/k940376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Jan 26, 1994
Decision date	Jun 2, 1994
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Seradyn, Inc.</b>
Location	Indianapolis, IN, US
Contact	ANDRIS INDRIKSONS
510(k) history	28 submissions · 28 cleared · 1988-2007

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