

**K823387 SOPHEIA GENTAMICIN EIA KIT**Dec 22, 1982  
37 days to decisionK823387 · Product code: **LCD** · Chemistry  
Source: <https://www.510kdatabase.net/k823387/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Nov 15, 1982
Decision date	Dec 22, 1982
Days to decision	37 days
Third-party review	No

**APPLICANT**

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Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
510(k) history	321 submissions · 321 cleared · 1976-2006

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Device record: <https://www.510kdatabase.net/k823387/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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