

**K940569 DIGOXIN FPIA REAGENT SET AND CALIBRATOR SET**Jul 13, 1994  
155 days to decisionK940569 · Product code: **KXT** · Chemistry  
Source: <https://www.510kdatabase.net/k940569/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Feb 8, 1994
Decision date	Jul 13, 1994
Days to decision	155 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	BARRY D ROBINS
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/k940569/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026