

**K901216 ENZYMUN TEST(R) DIGOXIN**May 31, 1990  
78 days to decisionK901216 · Product code: **KXT** · Toxicology  
Source: <https://www.510kdatabase.net/k901216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Mar 14, 1990
Decision date	May 31, 1990
Days to decision	78 days
Third-party review	No

**APPLICANT**

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Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
Contact	CHERI EMMONS
510(k) history	340 submissions · 340 cleared · 1976-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k901216/>; 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 22, 2026