

**K851032 COBAS FP REAGENTS FOR DIGOXIN & COBAS FP DIGOXIN C**Apr 3, 1985  
22 days to decisionK851032 · Product code: **KXT** · Toxicology  
Source: <https://www.510kdatabase.net/k851032/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Mar 12, 1985
Decision date	Apr 3, 1985
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	KAFADER II
510(k) history	296 submissions · 296 cleared · 1983-1999

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