

K970881 CEDIA DIGOXINMay 14, 1997
65 days to decisionK970881 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k970881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Mar 10, 1997
Decision date	May 14, 1997
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	Yvette Lloyd
510(k) history	340 submissions · 340 cleared · 1976-1999

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