FDA 510(k) Premarket Notification

K970883 CEDIA DIGOXIN II

CLEARED

May 21, 1997
72 days to decision

K970883 · Product code: **KXT** · Toxicology
Source: https://www.510kdatabase.net/k970883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Mar 10, 1997
Decision date	May 21, 1997
Days to decision	72 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