

K972794 DIGOXIN DG-II FPIA REAGENT SETJul 31, 1997
55 days to decisionK972794 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k972794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Jun 6, 1997
Decision date	Jul 31, 1997
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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