

K983323 DIGOXIN IMMUNOASSAYNov 12, 1998
51 days to decisionK983323 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k983323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Sep 22, 1998
Decision date	Nov 12, 1998
Days to decision	51 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Reagents, Inc.
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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