

K915602 SRI DIGOXIN ENZYME IMMUNOASSAYJan 17, 1992
35 days to decisionK915602 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k915602/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Dec 13, 1991
Decision date	Jan 17, 1992
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Serono-Baker Diagnostics, Inc.
Location	Winchester, VA, US
Contact	DAVID THOMAS
510(k) history	23 submissions · 23 cleared · 1988-1992

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