

**K934135 EMIT 2000 DIGOXIN ASSAY/CALIBRATORS
MODIFICATION**Apr 6, 1994
224 days to decisionK934135 · Product code: **KXT** · Toxicology
Source: <https://www.510kdatabase.net/k934135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Aug 25, 1993
Decision date	Apr 6, 1994
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	PAUL L ROGERS JR.
510(k) history	448 submissions · 447 cleared · 1976-2001

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