

K861394 EMIT DIGOXIN MOBILE PHASE SOLUTIONMay 29, 1986
45 days to decisionK861394 · Product code: **KXT** · Chemistry
Source: <https://www.510kdatabase.net/k861394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Apr 14, 1986
Decision date	May 29, 1986
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	ELEANOR V CHIU
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861394/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026