

**K884528 SERALYZER DIGOXIN ASSAY/TEST
MOD/CALIB/CONTR/AMES**Mar 8, 1989
131 days to decisionK884528 · Product code: **KXT** · Chemistry
Source: <https://www.510kdatabase.net/k884528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Oct 28, 1988
Decision date	Mar 8, 1989
Days to decision	131 days
Third-party review	No

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	ROSANNE M SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884528/>; 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 May 20, 2026