FDA 510(k) Premarket Notification

K963835 DIGOXIN ENZYME IMMUNOASSAY

CLEARED

Dec 10, 1996
77 days to decision

K963835 · Product code: **KXT** · Toxicology
Source: https://www.510kdatabase.net/k963835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Sep 24, 1996
Decision date	Dec 10, 1996
Days to decision	77 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k963835/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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