FDA 510(k) Premarket Notification

K932732 ACA(R) DIGOXIN ANALYTICAL TEST PACK (DGN)

CLEARED

Nov 15, 1993
161 days to decision

K932732 · Product code: **KXT** · Toxicology
Source: https://www.510kdatabase.net/k932732/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Jun 7, 1993
Decision date	Nov 15, 1993
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dupont Medical Products**
Location	Wilmington, DE, US
Contact	REBECCA S AYASH
510(k) history	28 submissions · 28 cleared · 1991-1995