FDA 510(k) Premarket Notification

K913240 DIGITOXIN (FPIA) KIT

CLEARED

Sep 6, 1991
46 days to decision

K913240 · Product code: **LFM** · Toxicology
Source: https://www.510kdatabase.net/k913240/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digitoxin (LFM)
Date received	Jul 22, 1991
Decision date	Sep 6, 1991
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tudor Laboratories, Inc.**
Location	Dallas, TX, US
Contact	ROBERT M DOWBEN
510(k) history	9 submissions · 9 cleared · 1989-1992