FDA 510(k) Premarket Notification

K042975 AMEDITECH IMMUTEST MULTI-DRUG SCREEN PANEL II

CLEARED

Dec 29, 2004
62 days to decision

K042975 · Product code: **DIS** · Toxicology
Source: https://www.510kdatabase.net/k042975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Oct 28, 2004
Decision date	Dec 29, 2004
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ameditech, Inc.**
Location	San Diego, CA, US
Contact	JOHN WU
510(k) history	14 submissions · 14 cleared · 2001-2011