FDA 510(k) Premarket Notification

K942552 THERAPEUTIC DRUG MONITORING CONTROL, UNASSAYED

CLEARED

Sep 9, 1994
101 days to decision

K942552 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k942552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	May 31, 1994
Decision date	Sep 9, 1994
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medi-Tech, Inc.**
Location	Mchenry, IL, US
Contact	SHING KWAN
510(k) history	36 submissions · 35 cleared · 1978-1996