FDA 510(k) Premarket Notification

K962165 COBAS-FP TDM CALIBRATION VERIFICATION TEST SET

CLEARED

Jun 26, 1996
22 days to decision

K962165 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k962165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jun 4, 1996
Decision date	Jun 26, 1996
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Roche Diagnostic Systems, Inc.**
Location	Mchenry, IL, US
Contact	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999