FDA 510(k) Premarket Notification

K934062 BIOTRACK THERAPEUTIC DRUG-MONITORING QUAL CONTROLS

CLEARED

Dec 29, 1993
132 days to decision

K934062 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k934062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Aug 19, 1993
Decision date	Dec 29, 1993
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Biotrack, Inc.**
Location	Sunnyvale, CA, US
Contact	BERNELLE SAPERSTEIN
510(k) history	16 submissions · 16 cleared · 1986-1993