FDA 510(k) Premarket Notification

K831500 TRI-LEVEL TDM CONTROL & I II III

CLEARED

Jun 30, 1983
50 days to decision

K831500 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k831500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	May 11, 1983
Decision date	Jun 30, 1983
Days to decision	50 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997