FDA 510(k) Premarket Notification

K821975 ORTHO*-BI-LEVEL ASSAYED WHOLE BLOOD TOX

CLEARED

Aug 27, 1982
52 days to decision

K821975 · Product code: **DIF** · Toxicology
Source: https://www.510kdatabase.net/k821975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jul 6, 1982
Decision date	Aug 27, 1982
Days to decision	52 days
Third-party review	No

APPLICANT

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