

K831500 TRI-LEVEL TDM CONTROL & I II IIIJun 30, 1983
50 days to decisionK831500 · 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k831500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026