

K821975 ORTHO*-BI-LEVEL ASSAYED WHOLE BLOOD TOXAug 27, 1982
52 days to decisionK821975 · 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

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Device record: <https://www.510kdatabase.net/k821975/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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