FDA 510(k) Premarket Notification

K823131 KOAGULAB 40-A AUTOMATED COAGULATION SYS

CLEARED

Dec 9, 1982
45 days to decision

K823131 · Product code: **KQG** · Hematology
Source: https://www.510kdatabase.net/k823131/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation (KQG)
Date received	Oct 25, 1982
Decision date	Dec 9, 1982
Days to decision	45 days
Third-party review	No

APPLICANT

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