

K901120 KOAGULAB 60-S COAGULATION SYSTEMMay 22, 1990
71 days to decisionK901120 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k901120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	Mar 12, 1990
Decision date	May 22, 1990
Days to decision	71 days
Third-party review	No

APPLICANT

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

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