

**K853328 KOAGULAB 16-S SEMI-AUTOMATED COAGULATION
SYS**Nov 5, 1985
89 days to decisionK853328 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k853328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Aug 8, 1985
Decision date	Nov 5, 1985
Days to decision	89 days
Third-party review	No

APPLICANT

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

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