

**K935748 ORTHO RECOMBIPLASTIN II W/ORTHO
RECOMBIPLASTIN II DILUENT**Apr 26, 1995
511 days to decisionK935748 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k935748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Dec 1, 1993
Decision date	Apr 26, 1995
Days to decision	511 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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