

**K940209 ORTHO ASSAYED REFERENCE PLASMA-NORMAL/  
PLASMA-ABNORMAL**May 11, 1995  
482 days to decisionK940209 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k940209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Jan 14, 1994
Decision date	May 11, 1995
Days to decision	482 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940209/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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