

**K901327 ORTHO CORRECTION REAGENTS**May 25, 1990  
65 days to decisionK901327 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k901327/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Mar 21, 1990
Decision date	May 25, 1990
Days to decision	65 days
Third-party review	No

**APPLICANT**

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

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