

K883688 ORTHO FACTOR XII DEFICIENT PLASMANov 1, 1988
64 days to decisionK883688 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k883688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Aug 29, 1988
Decision date	Nov 1, 1988
Days to decision	64 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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