

K963902 QUANTITATIVE FIBRINOGEN ASSAYNov 29, 1996
63 days to decisionK963902 · Product code: **GIS** · Hematology
Source: <https://www.510kdatabase.net/k963902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Sep 27, 1996
Decision date	Nov 29, 1996
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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