

**K953981 SYNTHASIL APTT REAGENT**Nov 30, 1995  
99 days to decisionK953981 · Product code: **GFO** · Hematology  
Source: <https://www.510kdatabase.net/k953981/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Aug 23, 1995
Decision date	Nov 30, 1995
Days to decision	99 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	BLANCHE CHIEN
510(k) history	126 submissions · 126 cleared · 1981-1997

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