

K955638 SYNTHAFAX APTT REAGENTApr 23, 1996
134 days to decisionK955638 · Product code: **GFO** · Hematology
Source: <https://www.510kdatabase.net/k955638/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Activated Partial Thromboplastin (GFO) |
| Date received | Dec 11, 1995 |
| Decision date | Apr 23, 1996 |
| Days to decision | 134 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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