

K843535 ORTHO BRAIN THROMBOPLASTIN DILUENTDec 12, 1984
96 days to decisionK843535 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k843535/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Time, Prothrombin (GJS) |
| Date received | Sep 7, 1984 |
| Decision date | Dec 12, 1984 |
| Days to decision | 96 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k843535/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026