

**K851641 THROMBOSIL SILICA ACTIVATED PTT REAGENT
THROMBOXIL**Jul 23, 1985
95 days to decisionK851641 · Product code: **MSJ** · Hematology
Source: <https://www.510kdatabase.net/k851641/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Apolipoproteins (MSJ) |
| Date received | Apr 19, 1985 |
| Decision date | Jul 23, 1985 |
| Days to decision | 95 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k851641/>; 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