

K962857 COAG-A-MATE MTXJan 22, 1997
184 days to decisionK962857 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k962857/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Coagulation, Automated (GKP) |
| Date received | Jul 22, 1996 |
| Decision date | Jan 22, 1997 |
| Days to decision | 184 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Organon Teknika Corp. |
| Location | Mchenry, IL, US |
| Contact | ANN M QUINN |
| 510(k) history | 130 submissions · 129 cleared · 1980-2000 |

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