

K991101 COAG-A-MATE MAXJun 1, 1999
61 days to decisionK991101 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k991101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	Apr 1, 1999
Decision date	Jun 1, 1999
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	REBECCA A RIVAS
510(k) history	130 submissions · 129 cleared · 1980-2000

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