

K952608 MDA SIMPLASTIN LSOct 6, 1995
121 days to decisionK952608 · Product code: **GJS** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jun 7, 1995
Decision date	Oct 6, 1995
Days to decision	121 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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