

K915746 SIMPLASTIN LFeb 12, 1992
51 days to decisionK915746 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k915746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Dec 23, 1991
Decision date	Feb 12, 1992
Days to decision	51 days
Third-party review	No
Summary / Statement	Statement

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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