

K974566 MDA SIMPLASTIN HTFFeb 24, 1998
81 days to decisionK974566 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k974566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Dec 5, 1997
Decision date	Feb 24, 1998
Days to decision	81 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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