

K925617 MDA PROTEIN ASSAYJan 27, 1994
447 days to decisionK925617 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k925617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 6, 1992
Decision date	Jan 27, 1994
Days to decision	447 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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