

K922156 LUCOR CONFIRMATORY REAGENTApr 6, 1993
334 days to decisionK922156 · Product code: **GIR** · Hematology
Source: <https://www.510kdatabase.net/k922156/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Russel Viper Venom (GIR)
Date received	May 7, 1992
Decision date	Apr 6, 1993
Days to decision	334 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gradipore , Ltd.
Location	Pymont, AU
Contact	MANUSU
510(k) history	4 submissions · 4 cleared · 1990-2000

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