

K940490 DV TEST AND DVV CONFIRMApr 5, 1995
426 days to decisionK940490 · Product code: **GIR** · Hematology
Source: <https://www.510kdatabase.net/k940490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Russel Viper Venom (GIR)
Date received	Feb 3, 1994
Decision date	Apr 5, 1995
Days to decision	426 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	American Diagnostica, Inc.
Location	Greenwich, CT, US
Contact	C LADA SOCHYNSKY
510(k) history	10 submissions · 10 cleared · 1994-2008

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