

**K935254 DVVTEST AND DVVCONFIRM LUPUS
ANTICOAGULANT NORMAL AND ABNORMAL CONTROL
PLASMA**Sep 19, 1994
322 days to decisionK935254 · Product code: **GIZ** · Hematology
Source: <https://www.510kdatabase.net/k935254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Control, Normal (GIZ)
Date received	Nov 1, 1993
Decision date	Sep 19, 1994
Days to decision	322 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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