

**K001352 REAADS IGG ANTI-PROTHROMBIN SEMI-
QUANTITATIVE TEST KIT**Apr 9, 2001
346 days to decisionK001352 · Product code: **DHC** · Immunology
Source: <https://www.510kdatabase.net/k001352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Systemic Lupus Erythematosus (DHC)
Date received	Apr 28, 2000
Decision date	Apr 9, 2001
Days to decision	346 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Corgenix, Inc.
Location	Westminster, CO, US
Contact	NANCI DEXTER
510(k) history	23 submissions · 23 cleared · 1998-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001352/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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