

**K001398 REAADS IGM ANTI-PROTHROMBIN SEMI-
QUANTITATIVE TEST KIT**Mar 30, 2001
331 days to decisionK001398 · Product code: **DHC** · Immunology
Source: <https://www.510kdatabase.net/k001398/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Systemic Lupus Erythematosus (DHC) |
| Date received | May 3, 2000 |
| Decision date | Mar 30, 2001 |
| Days to decision | 331 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/k001398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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