

**K013080 REAADS ANTI-BETA 2 GLYCOPROTEIN I IGG TEST
KIT**Sep 28, 2001
14 days to decisionK013080 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k013080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Sep 14, 2001
Decision date	Sep 28, 2001
Days to decision	14 days
Third-party review	No
Summary / Statement	Statement

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/k013080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026