

K034013 REAADS DSDNA QUANTITATIVE TEST KIT, MODEL 022-001

Jan 8, 2004
15 days to decision

K034013 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k034013/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Dec 24, 2003
Decision date	Jan 8, 2004
Days to decision	15 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.net

Device record: <https://www.510kdatabase.net/k034013/> 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