

K042680 RHIGENE HEP-ANA TEST SYSTEMNov 19, 2004
51 days to decisionK042680 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k042680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Sep 29, 2004
Decision date	Nov 19, 2004
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042680/> 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