

K834349 ANTI-NATIVE DNA ANTIBODYApr 19, 1984
128 days to decisionK834349 · Product code: **KTL** · Immunology
Source: <https://www.510kdatabase.net/k834349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Indirect Immunofluorescent Solid Phase (KTL)
Date received	Dec 13, 1983
Decision date	Apr 19, 1984
Days to decision	128 days
Third-party review	No

APPLICANT

Company	Sigma Chemical Co.
Location	Mchenry, IL, US
Website	https://www.sigmaaldrich.com
510(k) history	231 submissions · 231 cleared · 1976-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k834349/>; 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 May 14, 2026