

K820945 SERA FOR ANTINUCLEAR ANTIBODIESOct 26, 1982
203 days to decisionK820945 · Product code: **DHN** · Microbiology
Source: <https://www.510kdatabase.net/k820945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Apr 6, 1982
Decision date	Oct 26, 1982
Days to decision	203 days
Third-party review	No

APPLICANT

Company	Centers For Disease Control and Prevention
Location	Mchenry, IL, US
510(k) history	29 submissions · 25 cleared · 1981-2025

Centers For Disease Control and Prevention is the United States federal public health agency under the Department of Health and Human Services. Headquartered in Atlanta, Georgia, the CDC protects public health through disease control and prevention domestically and worldwide. The CDC has received FDA 510(k) clearances from total submissions since 1981. The agency's regulatory portfolio is dominated by Microbiology devices, representing 97% of submissions. Latest clearance activity in 2025 demonstrates continued engagement in FDA regulatory pathways. The CDC's cleared devi...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k820945/> 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 26, 2026