

K834241 ANA APPLELISAApr 4, 1984
120 days to decisionK834241 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k834241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Dec 6, 1983
Decision date	Apr 4, 1984
Days to decision	120 days
Third-party review	No

APPLICANT

Company	Apple Diagnostic Products
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1984-1985

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k834241/> 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 July 1, 2026