

K782041 FIAX TEST KITJan 3, 1979
27 days to decisionK782041 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k782041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Dec 7, 1978
Decision date	Jan 3, 1979
Days to decision	27 days
Third-party review	No

APPLICANT

Company	Idt, A Division of Whittaker M.A. Bioproducts
Location	Mchenry, IL, US
510(k) history	5 submissions · 5 cleared · 1977-1986

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Device record: <https://www.510kdatabase.net/k782041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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