

K822397 ANA HEP-2 FLUORO-KITSep 21, 1982
42 days to decisionK822397 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k822397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Aug 10, 1982
Decision date	Sep 21, 1982
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Clinical Sciences, Inc.
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1977-1990

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Device record: <https://www.510kdatabase.net/k822397/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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