

K780899 FLUORESCENT ANTI-NATIVE DNA TESTSep 7, 1978
97 days to decisionK780899 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k780899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Jun 2, 1978
Decision date	Sep 7, 1978
Days to decision	97 days
Third-party review	No

APPLICANT

Company	Kallestad Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	92 submissions · 92 cleared · 1976-1986

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Device record: <https://www.510kdatabase.net/k780899/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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