

K842484 LEAP LE TEST KITJul 11, 1984
16 days to decisionK842484 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k842484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Jun 25, 1984
Decision date	Jul 11, 1984
Days to decision	16 days
Third-party review	No

APPLICANT

Company	Cooper Biomedical, Inc.
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1983-1987

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Device record: <https://www.510kdatabase.net/k842484/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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