

K883883 ANTINUCLEAR ANTIBODY (ANA) TEST (HEP-2 CELLS)Oct 27, 1988
44 days to decisionK883883 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k883883/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Sep 13, 1988
Decision date	Oct 27, 1988
Days to decision	44 days
Third-party review	No

APPLICANT

Company	Immco Diagnostics, Inc.
Location	Buffalo, NY, US
Contact	RUSSELL NISENGARD
510(k) history	55 submissions · 55 cleared · 1988-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883883/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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