

K905531 LUPUS(LE)-LATEX TESTJan 25, 1991
46 days to decisionK905531 · Product code: **LKI** · Immunology
Source: <https://www.510kdatabase.net/k905531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, Chlamydia Spp. (LKI)
Date received	Dec 10, 1990
Decision date	Jan 25, 1991
Days to decision	46 days
Third-party review	No

APPLICANT

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

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