

K921421 LEGIONELLA REAGENS FOR DIRECT FLUORESCENT ANTIBODY

Jul 28, 1992
126 days to decision

K921421 · Product code: **LHL** · Microbiology
Source: <https://www.510kdatabase.net/k921421/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Antibody, Legionella, Direct & Indirect Fluorescent (LHL)
Date received	Mar 24, 1992
Decision date	Jul 28, 1992
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pro-Lab, Inc.
Location	Mchenry, IL, US
Contact	JOACHIM SPARKUHL
510(k) history	27 submissions · 26 cleared · 1984-1995

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Device record: <https://www.510kdatabase.net/k921421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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