K921421 LEGIONELLA REAGENS FOR DIRECT FLUORESCENT ANTIBODY

CLEARED

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