FDA 510(k) Premarket Notification

K863681 PATHFINDER(TM) DIRECT ANTIGEN DETECTION SYSTEM

CLEARED

Dec 3, 1986
75 days to decision

K863681 · Product code: **LJP** · Microbiology
Source: https://www.510kdatabase.net/k863681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Fluorescent, Chlamydia Trachomatis (LJP)
Date received	Sep 19, 1986
Decision date	Dec 3, 1986
Days to decision	75 days
Third-party review	No

APPLICANT

Company	**Kallestad Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	QUINLAN SMITH
510(k) history	92 submissions · 92 cleared · 1976-1986