FDA 510(k) Premarket Notification

K884517 PATHFINDER(TM) CHLAMYDIA EIA DETECT KIT/MODIFIED

CLEARED

Nov 30, 1988
34 days to decision

K884517 · Product code: **LJC** · Microbiology
Source: https://www.510kdatabase.net/k884517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, (chlamydiae Group) (LJC)
Date received	Oct 27, 1988
Decision date	Nov 30, 1988
Days to decision	34 days
Third-party review	No

APPLICANT

Company	**Kallestad Diag, A Div. of Erbamont, Inc.**
Location	Chaska, MN, US
Contact	QUINLAN SMITH
510(k) history	58 submissions · 58 cleared · 1987-1991