FDA 510(k) Premarket Notification

K853738 ORTHO CHLAMYDIA DIRECT DETECTION (FA) TEST

CLEARED

Dec 6, 1985
91 days to decision

K853738 · Product code: **LJP** · Microbiology
Source: https://www.510kdatabase.net/k853738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Fluorescent, Chlamydia Trachomatis (LJP)
Date received	Sep 6, 1985
Decision date	Dec 6, 1985
Days to decision	91 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
Contact	LARRY D MCCLAIN
510(k) history	126 submissions · 126 cleared · 1981-1997