

**K853738 ORTHO CHLAMYDIA DIRECT DETECTION (FA) TEST**Dec 6, 1985  
91 days to decisionK853738 · 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	<b>Ortho Diagnostic Systems, Inc.</b>
Location	Carpinteria, CA, US
Contact	LARRY D MCCLAIN
510(k) history	126 submissions · 126 cleared · 1981-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853738/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026