

K872628 GONOSPOT* DNA PROBE CULTURE CONFIRMATION TESTDec 21, 1987
168 days to decisionK872628 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k872628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Jul 6, 1987
Decision date	Dec 21, 1987
Days to decision	168 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k872628/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026