

K961191 COLISCREENJun 17, 1996
83 days to decisionK961191 · Product code: **JTO** · Microbiology
Source: <https://www.510kdatabase.net/k961191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Discs, Strips And Reagents, Microorganism Differentiation (JTO)
Date received	Mar 26, 1996
Decision date	Jun 17, 1996
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hardy Diagnostics
Location	Santa Maria, CA, US
Contact	MELISSA M TRAYLOR, RAC
510(k) history	109 submissions · 109 cleared · 1993-2026

Hardy Diagnostics is an American health care company headquartered in Santa Maria, California. The company manufactures bacteriological culture media, reagents, automated microscope slide staining machines, and rapid identification kits for microbiological testing. Hardy Diagnostics has received FDA 510(k) clearances from total submissions since 1993. The company specializes exclusively in Microbiology devices, with its most recent clearance in 2025. Recent cleared devices include antibiotic susceptibility testing disks and viral transport media. The company manufactures ...

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