

K994135 HARDYDISK ERYTHROMYCIN, 15MCGFeb 16, 2000
71 days to decisionK994135 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k994135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Dec 7, 1999
Decision date	Feb 16, 2000
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hardy Diagnostics
Location	Santa Maria, CA, US
Contact	MELISSA M TRAYLOR
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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