

K011385 HARDKYDISK NEOMYCIN, 30 MCGMay 18, 2001
11 days to decisionK011385 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k011385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	May 7, 2001
Decision date	May 18, 2001
Days to decision	11 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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