

K172621 HardyDisk Meropenem/Vaborbactam 20/10µg (MEV30)Oct 3, 2017
33 days to decisionK172621 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k172621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Aug 31, 2017
Decision date	Oct 3, 2017
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hardy Diagnostics
Location	Santa Maria, CA, US
Contact	Andre Hsiung
510(k) history	108 submissions · 108 cleared · 1993-2025

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 ...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172621/> 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 31, 2026