

K250956 HardyDisk AST Gepotidacin 10µg (GEP10)

Jun 26, 2025
87 days to decision

K250956 · Product code: **JTN** · Microbiology
Source: <https://www.510kdatabase.net/k250956/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Mar 31, 2025
Decision date	Jun 26, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

APPLICANT

Company	Hardy Diagnostics
Location	Santa Maria, CA, US
Contact	Lauren Hamilton
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 ...