

**K080019 HARDYDISK AST DORIPENEM 10 UG**Jan 29, 2008  
26 days to decisionK080019 · Product code: **JTN** · Microbiology  
Source: <https://www.510kdatabase.net/k080019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Jan 3, 2008
Decision date	Jan 29, 2008
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hardy Diagnostics</b>
Location	Santa Maria, CA, US
Contact	WENDY PHILLIPS
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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