

**K191931 HardyDisk AST Imipenem/relebactam 10/25µg  
(IMR10/25)**Jul 31, 2019  
12 days to decisionK191931 · Product code: JTN · Microbiology  
Source: <https://www.510kdatabase.net/k191931/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Jul 19, 2019
Decision date	Jul 31, 2019
Days to decision	12 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hardy Diagnostics</b>
Location	Santa Maria, CA, US
Contact	Anna Klavins
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 ...

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