

**K170127 HardyDisk Ceftolozane/Tazobactam, (30/10 ug)-C/T40**Mar 14, 2017  
60 days to decisionK170127 · Product code: JTN · Microbiology  
Source: <https://www.510kdatabase.net/k170127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Jan 13, 2017
Decision date	Mar 14, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hardy Diagnostics</b>
Location	Santa Maria, CA, US
Contact	Rianna Malherbe
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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