

**K192326 HardyDisk AST Lefamulin 20µg (LMU20)**Sep 19, 2019  
23 days to decisionK192326 · Product code: JTN · Microbiology  
Source: <https://www.510kdatabase.net/k192326/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Aug 27, 2019
Decision date	Sep 19, 2019
Days to decision	23 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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Device record: <https://www.510kdatabase.net/k192326/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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