

**K102922 HARDYCHROM MRSA**May 4, 2011  
215 days to decisionK102922 · Product code: **JSO** · Microbiology  
Source: <https://www.510kdatabase.net/k102922/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar (JSO)
Date received	Oct 1, 2010
Decision date	May 4, 2011
Days to decision	215 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hardy Diagnostics</b>
Location	Santa Maria, CA, US
Contact	RENE CLASEN
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 ...