

K190553 HardyCHROM CREApr 29, 2019
55 days to decisionK190553 · Product code: **JSO** · Microbiology
Source: <https://www.510kdatabase.net/k190553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar (JSO)
Date received	Mar 5, 2019
Decision date	Apr 29, 2019
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hardy Diagnostics
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 ...