

K160512 HardyCHROM ESBLNov 15, 2016
265 days to decisionK160512 · Product code: **JSO** · Microbiology
Source: <https://www.510kdatabase.net/k160512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar (JSO)
Date received	Feb 24, 2016
Decision date	Nov 15, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hardy Diagnostics
Location	Santa Maria, CA, US
Contact	ANDRE HSIUNG
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 ...
