

**K170586 Strep B Carrot Broth One-Step**May 22, 2017  
83 days to decisionK170586 · Product code: **PQZ** · Microbiology  
Source: <https://www.510kdatabase.net/k170586/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gbs Culture Media, Selective And Differential (PQZ)
Date received	Feb 28, 2017
Decision date	May 22, 2017
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hardy Diagnostics</b>
Location	Santa Maria, CA, US
Contact	Christopher Massey
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 ...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170586/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026