

**K170481 Strep B Carrot Broth Kit**May 16, 2017  
89 days to decisionK170481 · Product code: **PQZ** · Microbiology  
Source: <https://www.510kdatabase.net/k170481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gbs Culture Media, Selective And Differential (PQZ)
Date received	Feb 16, 2017
Decision date	May 16, 2017
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hardy Diagnostics</b>
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 ...

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