

K242820 Puritan PurSafe Plus Collection and Transport SystemMay 27, 2025
251 days to decisionK242820 · Product code: **QBD** · Microbiology
Source: <https://www.510kdatabase.net/k242820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Nucleic Acid Storage And Stabilization Device (QBD)
Date received	Sep 18, 2024
Decision date	May 27, 2025
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Puritan Medical Products, LLC
Location	Guilford, ME, US
Contact	Mehdi Karamchi
Website	https://www.puritanmedproducts.com/
510(k) history	7 submissions · 7 cleared · 2012-2025

Puritan Medical Products, LLC is an American family-owned manufacturer known worldwide for specimen collection and transport systems. The company operates with a manufacturing facility in Guilford, Maine, and specializes in Microbiology devices for diagnostics and clinical applications. Puritan has received FDA 510(k) clearances from total submissions since 2012. The company's regulatory portfolio focuses entirely on Microbiology devices, including collection and transport systems with various culture media formulations. The latest clearance in 2025 demonstrates continued...