

K162284 Puritan Fecal Opti-Swab Collection and Transport System

Nov 4, 2016
81 days to decisionK162284 · Product code: **JSM** · Microbiology
Source: <https://www.510kdatabase.net/k162284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Non-propagating Transport (JSM)
Date received	Aug 15, 2016
Decision date	Nov 4, 2016
Days to decision	81 days
Third-party review	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...

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Device record: <https://www.510kdatabase.net/k162284/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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