FDA 510(k) Premarket Notification

CLEARED

K131630 PURITAN AMIES MEDIUM COLLECTION AND TRANSPORT SYSTEM

Oct 21, 2013
139 days to decision

K131630 · Product code: **LIO** · Microbiology
Source: https://www.510kdatabase.net/k131630/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Specimen Collection (LIO)
Date received	Jun 4, 2013
Decision date	Oct 21, 2013
Days to decision	139 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...