

**K142821 PAXgene Blood DNA Tube**Sep 9, 2015  
344 days to decisionK142821 · Product code: **PJE** · Toxicology  
Source: <https://www.510kdatabase.net/k142821/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood/plasma Collection Device For Dna Testing (PJE)
Date received	Sep 30, 2014
Decision date	Sep 9, 2015
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Preanalytix GmbH</b>
Location	Franklin Lakes, NJ, US
Contact	Pasquale Amato
510(k) history	4 submissions · 3 cleared · 2005-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142821/> 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 May 27, 2026