

**K231469 PAXgene® Blood DNA Tube**Jun 21, 2023  
30 days to decisionK231469 · Product code: **PJE** · Chemistry  
Source: <https://www.510kdatabase.net/k231469/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Blood/plasma Collection Device For Dna Testing (PJE)
Date received	May 22, 2023
Decision date	Jun 21, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231469/> 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