FDA 510(k) Premarket Notification

K231469 PAXgene® Blood DNA Tube

CLEARED

Jun 21, 2023
30 days to decision

K231469 · 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	**Preanalytix GmbH**
Location	Franklin Lakes, NJ, US
Contact	Alexandra Kirby
510(k) history	4 submissions · 3 cleared · 2005-2023