FDA 510(k) Premarket Notification

K142821 PAXgene Blood DNA Tube

CLEARED

Sep 9, 2015
344 days to decision

K142821 · Product code: **PJE** · Toxicology
Source: https://www.510kdatabase.net/k142821/

SUBMISSION DETAILS

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

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