

K192944 AncestryDNA Factor V Leiden Genetic Health Risk TestAug 13, 2020
300 days to decisionK192944 · Product code: **PTA** · Hematology
Source: <https://www.510kdatabase.net/k192944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Genetic Variant Detection And Health Risk Assessment System (PTA)
Date received	Oct 18, 2019
Decision date	Aug 13, 2020
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ancestry Genomics, Inc.
Location	San Francisco, CA, US
Contact	Raajdeep Venkatesan
510(k) history	2 submissions · 2 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192944/>. Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026