

K223597 23andMe® Personal Genome Service® (PGS®) Genetic Health Risk Report for BRCA1/BRCA2 (Selected Variants)

Aug 31, 2023
272 days to decision

K223597 · Product code: **QAZ** · Pathology
Source: <https://www.510kdatabase.net/k223597/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cancer Predisposition Risk Assessment System (QAZ)
Date received	Dec 2, 2022
Decision date	Aug 31, 2023
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	23AndMe, Inc.
Location	Mountain View, CA, US
Contact	Marianna Frendo
Website	http://www.23andme.com
510(k) history	8 submissions · 5 cleared · 2017-2023

23AndMe, Inc. is a consumer genetics company offering DNA testing services for ancestry, traits, and health insights. Based in Mountain View, the company has sold over 12 million kits and maintains one of the largest reference datasets in the world for genetic analysis. The company has received FDA 510(k) clearances from total submissions between 2017 and 2023. Cleared devices span chemistry and medical genetics categories, including pharmacogenetic reports and genetic health risk assessments. This represents a historical regulatory record; no clearances have been issued ...