FDA 510(k) Premarket Notification

CLEARED

K221885 23andMe Personal Genome Service (PGS) Pharmacogenetic Reports

Oct 26, 2022
119 days to decision

K221885 · Product code: **QDJ** · Chemistry
Source: https://www.510kdatabase.net/k221885/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Direct-to-consumer Access Pharmacogenetic Assessment System (QDJ)
Date received	Jun 29, 2022
Decision date	Oct 26, 2022
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	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 ...