

K193492 23andMe Personal Genome Service (PGS) Pharmacogenetic Reports

Aug 17, 2020
244 days to decisionK193492 · Product code: QDJ · Chemistry
Source: <https://www.510kdatabase.net/k193492/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Direct-to-consumer Access Pharmacogenetic Assessment System (QDJ)
Date received	Dec 17, 2019
Decision date	Aug 17, 2020
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	23AndMe, Inc.
Location	Mountain View, CA, US
Contact	Lisa Charter
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 ...

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Device record: <https://www.510kdatabase.net/k193492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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