FDA 510(k) Premarket Notification

CLEARED

K182784 MUTYH-Associated Polyposis (MAP)

Jan 18, 2019
109 days to decision

K182784 · Product code: **QAZ** · Medical Genetics
Source: https://www.510kdatabase.net/k182784/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cancer Predisposition Risk Assessment System (QAZ)
Date received	Oct 1, 2018
Decision date	Jan 18, 2019
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**23AndMe, Inc.**
Location	Mountain View, CA, US
Contact	Sarah Rys
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 ...