

First Look: FDA De Novo Classification of the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2

Approves marketing of 23andMe's direct-to-consumer genetic test for selected variants of the *BRCA1* and *BRCA2* mutations associated with breast cancer and establishes a new category for this device and similar devices.

Updated last **April 12, 2018**
for the 03/06/2018 approval.

WHAT IT DOES

The [Center for Devices and Radiological Health](#), under the Food and Drug Administration (FDA), has [determined](#) that 23andMe's direct-to-consumer genetic test for selected variants of the breast cancer-associated genes *BRCA1* and *BRCA2* is a [Class II](#) device and is approved for immediate marketing. After review of the test, the FDA determined the test can accurately identify the specific genetic variants from a saliva sample and has reproducible results. In granting this approval, the FDA also defined a new generic category, "Cancer Predisposition Risk Assessment System for *BRCA1/BRCA2* Select Variants," for approving similar devices that may be introduced to the market in the future.

As part of its approval, the FDA established "special control" criteria to ensure safety and efficacy of the device. Broadly, the FDA is requiring measures to help the consumer understand the device, the test system, and the scope and limitations of the interpretation of the test results. Many of these controls are carried out through requirements to label the device and results with warnings and statements explaining the limitations of the device and results, and to provide hyperlinks for consumers to get more information.

RELEVANT SCIENCE

[BRCA1](#) and [BRCA2](#) are genes that, when mutated, are associated with increased risk for developing breast, ovarian, and prostate cancer. Not all mutations in these genes are strongly associated with an increase risk for developing cancer, and genetic testing showing a mutation [does not](#) conclusively mean the individual will develop cancer.

STATUS

23andMe was notified of this decision on March 6, 2018. The correspondence from the FDA grants immediate market approval of the device. A formal rule establishing the new category of medical device will be published by the FDA in the *Federal Register* in the coming months.

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RECOMMENDED CITATION

Duke SciPol, "First Look: FDA De Novo Classification of the 23andMe PGS Genetic Health Risk Report for BRCA1/BRCA2" available at <http://scipol.duke.edu/content/first-look-fda-de-novo-classification-23andme-pgs-genetic-health-risk-report->

[brca1brca2](#) (04/12/2018).

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