FDA 510(k) Premarket Notification

CLEARED

K163367 GenetiSure Dx Postnatal Assay

Aug 11, 2017
254 days to decision

K163367 · Product code: **PFX** · Medical Genetics
Source: https://www.510kdatabase.net/k163367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Microarray-based, Genome-wide, Postnatal Chromosomal Abnormality Detection (PFX)
Date received	Nov 30, 2016
Decision date	Aug 11, 2017
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Agilent Technologies, Inc.**
Location	Pittsburgh, PA, US
Contact	Lois Nakayama
Website	http://www.agilent.com
510(k) history	30 submissions · 30 cleared · 1985-2017

Agilent Technologies, Inc. is an American global company that provides instruments, software, services, and consumables for laboratories. Headquartered in Santa Clara, California, Agilent was established in 1999 as a spin-off from Hewlett-Packard. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent the dominant focus, accounting for approximately 80% of regulatory submissions. Agilent's FDA 510(k) clearance history spans from 1985 to 2017, establishing a long track record in medical device regulation. Notable cleared dev...