23andMe works with FDA, bets on science

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis.

Last week, privately held 23andMe launched an approved Personal Genome Service (PGS). The company, which said it had worked closely with the FDA to validate its DNA analysis offerings, had received a stern warning letter from the agency in 2013 about its direct-to-consumer (DTC) spit kits for DNA collection and reports generated from gene analysis data.

“I am hopeful for 2015, it has been quite a transformation for the company, to really change and go through this entire process,” noted CEO Anne Wojcicki, who added that 23andMe revamped its approach to communicating and dealing with the FDA. The result: in February it won its first approval for a test for Bloom syndrome. Along with this authorization, the FDA also classified carrier screening tests as class II devices, which the agency intends to exempt from premarket review.

“We had to make a decision as a company whether we were going to stay in the business of personal genomic analysis,” said Angela Calman-Wonson, 23andMe’s vp of communications. “The classification gave us a road map for what we still had to go through for the validation process. The company went with genomic detection of autosomal recessive carrier status because it was the best understood area of genetics and emphasized that it was not testing for the diseases [themselves].”

Read full, original post: 23andMe Goes All In For Science