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Bradley Merrill Thompson Quoted in "FDA Clears Path for Some Genetic Tests to Skip 510(k) Process"

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Bradley Merrill Thompson, Member of the Firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office, was quoted in *Inside Health Policy's FDA Week*, in "FDA Clears Path for Some Genetic Tests to Skip 510(k) Process," by David Hood.

Following is an excerpt:

In the first six weeks of 2015, FDA released three separate guidance documents on devices it intends to deregulate. Bradley Merrill Thompson, an attorney for Epstein Becker & Green who serves as general counsel for the mHealth Regulatory Coalition, told *FDA Week* that the guidance documents signal that the agency is interested in spurring innovation. FDA's approval of 23andMe's application blazes the trail for other DTC genetic testing products to bypass the 510(k) process, he said.

"To me, the press release says that for the whole category, they plan to leave it in Class II, but exempt it from the most burdensome aspect of Class II, which is 510(k) requirement," said Thompson. "And that's pretty remarkable."

People

Bradley Merrill Thompson
Member of the Firm
Regulatory Strategy, Product Development, and Product Approvals
Washington, DC
202-861-1817
bthompson@ebglaw.com

Thompson said the leadership at FDA's Center for Devices and Radiological Health is genuinely interested in innovative products and is committed to making sure the agency can get them to market as quickly as possible. He said the change in attitude at CDRH had also to do in part with industry's cooperation with FDA in providing sufficient data to support expeditious approvals.

The interesting thing, Thompson said, was that 23andMe even received a warning letter in 2013 from FDA, demanding the company stop marketing its product because it was not granted clearance. The agency called the marketing of the device in violation of the Federal Food, Drug and Cosmetic Act. The letter said 23andMe's product is intended to diagnose diseases or other conditions or in the cure, mitigation, treatment, or prevention of disease.