EPSTEIN BECKER GREEN

# Evenhanded FDA Enforcement, *in* Medical Device and Diagnostic Industry

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Bradley Merrill Thompson

**Bradley Merrill Thompson,** a Member of the Firm in the Health Care and Life Sciences practice, in the Washington, DC, office, wrote an article titled "Wanted: Evenhanded FDA Enforcement."

## Following is an excerpt:

Just about everyone in the medical device industry knows that companies are not allowed to begin selling their medical devices until they have obtained the necessary FDA clearance. But while that's been the case since Congress enacted the 1976 Medical Device Amendments, recent FDA inaction in the context of mobile medical apps is causing confusion. If the rule has somehow changed, FDA should let everyone know that. But if the rule has not changed, FDA needs to apply the rule consistently.

**Background**

I first raised the issue of consistent enforcement about a year ago, when I wrote a post on *MD+DI* asking FDA to start applying its enforcement actions more evenly with companies that were plainly selling medical devices without the required FDA clearance. At the time, I was focused on mobile medical apps that clearly met the definition of a medical device, and I illustrated my point with the uChek App, a mobile app that caused a cell phone to function as a urinalysis instrument. Back then, the company making the uChek app, Biosense, was making medical claims about testing urine for occult blood and glucose, among other

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things, while disclaiming that its product was a medical device. A couple of months after I wrote that post, FDA took action, sending the company an enforcement letter.