Epstein Becker Green's Unpacking Averages Report "Casts Doubt on Value of US FDA's Breakthrough Devices Program"

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BioWorld cited the *Health Law Advisor* blog post, "Unpacking Averages: Assessing Whether FDA's Breakthrough Device Designation Is Helpful," authored by **Bradley Merrill Thompson,** Strategic Advisor with EBG Advisors and Member of the Firm in the Health Care & Life Sciences practice at Epstein Becker Green, in the article "Report Casts Doubt on Value of US FDA's Breakthrough Devices Program," by Mark McCarty. *(Read the full version – subscription required.)*

Following is an excerpt:

The U.S. FDA's breakthrough devices program has engendered a tremendous amount of interest on the part of industry, but an Aug. 2 report by the law practice of Epstein Becker & Green P.C., suggests that the value of the program may be overblown. The report states that only 44 of the more than 600 devices that have been granted access to the program have successfully emerged – a number that was updated Aug. 3 by the FDA to 54 – which is still a rate that suggests that the breakthrough devices program might not be as helpful as billed.

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