New Developments in FDA Regulation of AI

Medical Device and Diagnostic Industry (MD+DI)

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Bradley Merrill Thompson, Strategic Advisor with EBG Advisors and Member of the Firm at Epstein Becker Green, authored an article in *Medical Device and Diagnostic Industry (MD+DI),* titled "New Developments in FDA Regulation of AI."

Following is an excerpt:

For the last several years, the U.S. FDA and its stakeholders have been calling for a new regulatory approach for artificial intelligence (AI) used in healthcare. Pretty much everyone seems to agree that AI is different from other medical devices, due in part to the fact that AI learns on the job. The fact that such learning changes performance over time and the fact that the company might make frequent updates both suggest the need for a new regulatory approach.

In light of that general agreement, what progress are we making toward that goal? This article focuses on some of FDA's initiatives over the last year and specifically examines the agency's efforts to define the scope of its regulation of AI, the process and substance of FDA premarket reviews, and finally a few special issues associated with autonomous AI.

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