Cristales in MedTech Dive: Four Questions About the FDA's Approach to Generative AI

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As the FDA develops guidance for generative AI in medical devices, regulators are weighing how to evaluate the technology's safety and efficacy and monitor its performance over time. Haynes Boone Counsel **Kayla Cristales** spoke with *MedTech Dive* about the FDA's discussion paper, noting that the agency is recognizing the distinct regulatory challenges presented by the technology.

Read an excerpt below.

Kayla Cristales, an attorney with Haynes Boone, sees the paper as a step in the right direction, adding that it was an "open acknowledgement that this is a totally different beast." …

"I think what they may end up doing is heavily relying on the companies themselves to provide updates." …

"I think they're going to have to come up with some type of a way to stay on top of and to monitor the evolution of these devices," Cristales said. "I think what they may end up doing is heavily relying on the companies themselves to provide updates." …

Read the full *MedTech Dive* article **here**.