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QUOTED. April 16, 2018. Jeffrey Shapiro.

by

Check out what attorney Jeffrey Shapiro had to say about US FDA's recent draft guidance laying out an alternative 510(k) route that bypasses predicate comparisons.

"I think they are addressing a real issue in trying to improve the abbreviated 510(k) process, but it's not a silver bullet that will dramatically improve the effectiveness of the 510(k) process across the board." – Jeffrey Shapiro, director, Hyman, Phelps & McNamara

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