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QUOTED. Dec. 13, 2018. Quynh Hoang And Elaine Tseng.

by

FDA is considering publishing a list of devices 510(k)-cleared based on predicates over ten-years-old to encourage companies to adopt new predicates. In a joint written response to *Medtech Insight's* questions, medical device regulatory experts with law firm King & Spalding said an age-based cut-off will not necessarily address the problem FDA is trying to address.

"FDA should consider the reasonability of applying a bright-line rule for the age of predicates to other devices for which the referenced standards are not applicable, or where predicates, notwithstanding their age, may still represent the current state of technology. As the agency seems to acknowledge, setting an appropriate bright-line age to define 'older' predicates may be difficult as a general matter." - Quynh Hoang and Elaine Tseng, King & Spalding

- Find out More: [An FDA Age-Based Predicate Policy Would Be Arbitrary, Reg Experts Complain](#)

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