

28 May 2019 | News

QUOTED. 28 May 2019. Bradley Merrill Thompson.

by

The US Food and Drug Administration is asking de novo and 510(k) sponsors with medical software products to consider being test subjects for the agency's upcoming new precertification pathway for digital health products. See what Bradley Merrill Thompson, an attorney with Epstein Becker & Green, said about it here.

"Given the extraordinarily slow pace of and little progress in developing the program over the last couple of years, and the fact that they will need legislative authority, the future of the program is quite uncertain." –Bradley Merrill Thompson, attorney, Epstein Becker & Green

• Find out more: Testing The Limits: Software De Novo, 510(k) Volunteers Wanted By US FDA

<u>Click here</u> for a free trial of Medtech Insight