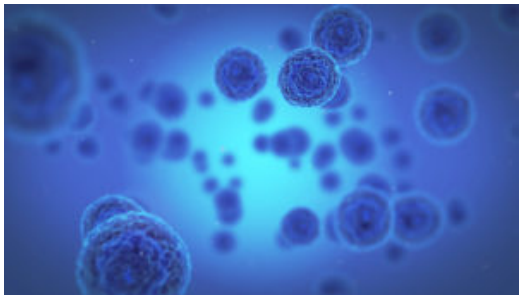
The Long (Un)Winding Road Part 2: FDA's Final Transition Guidances for COVID-19 Devices



On March 24, 2023, the FDA's Center for Devices and Radiological Health announced the issuance of two much anticipated final guidances that describe the Agency's transition plans for medical devices that fall within certain COVID-19 enforcement policies or that were issued emergency use authorizations ("EUA"s):

- **Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency** (the "Enforcement Policies Final Guidance")
- **Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)** (the "EUA Transition Final Guidance")

The guidances follow the announcement in early 2023 that the Biden Administration plans to wind-down a number of pandemic-related programs and to allow the COVID-19 public health emergency ("PHE") declaration, which has been in effect since January 2020, to expire on May 11, 2023.

We summarize some of the key takeaways from FDA's finalized transition plans. Read the client alert **here**.