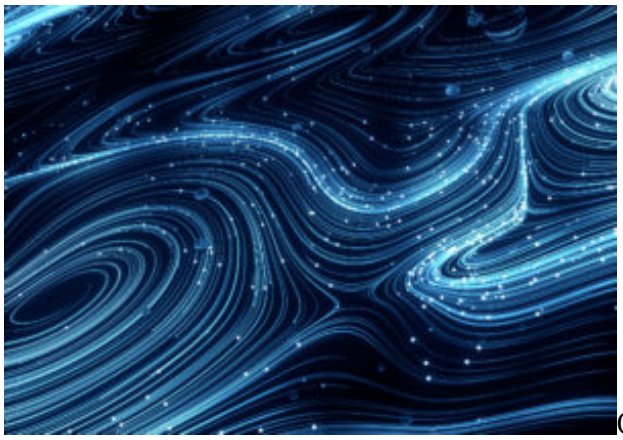
Modernizing the FDA's 510(k) Program for Medical Devices: Selection of Predicate Devices and Use of Clinical Data in 510(k) Submissions

 On September 6, 2023, the US Food and Drug Administration (FDA) released a trio of draft guidances in its efforts to "strengthen and modernize" the 510(k) Program and provide for more "predictability, consistency, and transparency" for the 510(k) premarket review process. In this post, we discuss the two new draft guidances with broad applicability to the 510(k) Program:

- "**Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission**"
- "**Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions**"

The two draft guidances address a number of fundamental issues of concern with the 510(k) process.

Read the full client alert **here**.