

## 510(k) Modernization Readiness Checklist

- Confirm the device qualifies for the 510(k) pathway as per the modernized FDA 510(k)
- Review applicable FDA draft and final guidances related to 510(k) modernization
- Choose the appropriate 510(k) submission type-  
Traditional/Special/Abbreviated
- Select a predicate device with appropriate intended use safety, performance, and technological characteristics
- Document a clear scientific rationale for predicate selection and substantial equivalence
- Assess whether clinical data or real-world evidence is needed based on device risk, technological differences and novelty
- Ensure performance testing, including bench tests, software validation and other applicable verification activities, align with current FDA expectations
- Validate that risk management and benefit-risk analysis are complete and up to date
- Confirm labeling, indications for use, and claims are consistent with the predicate device and supporting evidence
- Prepare the submission using the mandatory eSTAR electronic format, required for all 510(k)s since Oct 1, 2023, unless exempt).