

510(k) Submission Readiness Checklist



- **Device Description**
 - Clear summary of device, components, materials, and function.
- **Intended Use & Indications for Use**
 - Precise statements matching your clinical claims.
- **Predicate Device Identification**
 - Selected predicate with rationale showing similarity.
- **Comparison to Predicate**
 - Tables comparing technological characteristics and performance.
- **Performance Data**
 - Bench, biocompatibility, software, and any applicable test results.
- **Risk Analysis**
 - Hazard analysis and mitigation tied to design controls.
- **Labeling & Instructions for Use**
 - Draft labels, IFU, warnings, and promotional materials.
- **Standards & Guidance Compliance**
 - List applicable FDA guidance and consensus standards used.
- **Cover Letter & Administrative Forms**
 - Signed applicable FDA forms, cover letter, and user fee receipt.