FDA 510(k) Readiness Checklist: From Planning to Clearance

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Phase 1: Strategic Foundation

- Define product's unique value proposition and clinical relevance
- Map regulatory pathways in key target markets (US & global)
- Conduct a gap analysis of technical documentation vs FDA requirements
- Confirm applicable FDA product codes and regulation numbers
- Identify applicable guidance documents and recognized consensus standards
- Assess if device modifications require a new 510(k)

Phase 2: Design Inputs & Risk Controls

- Develop complete and traceable User Needs & Design Inputs (URS, DDS)
- Integrate Human Factors Engineering considerations early (if applicable)
- Document Design Verification & Validation (V&V) activities
- Create a comprehensive Hazard Analysis & FMEA (aligned with ISO 14971)
- Define usability testing needs (per FDA's HFE guidance)

Phase 3: Clinical & Scientific Rationale

- Prepare clinical justification for equivalence claims (if no clinical study)
- Compile literature review or real-world evidence (if available)
- Justify testing methods selected using scientific rationale
- For SaMD, define Level of Concern and cybersecurity controls
- Ensure software documentation aligns with FDA's 2023 guidance

Phase 4: Full Submission Compilation

- Write Executive Summary highlighting device, predicate, and performance
- Include device photos, engineering drawings, and key specs
- Add Design Controls Summary and traceability matrix
- Compile summary tables for bench, biocompatibility, EMC, and software tests
- Verify completeness using FDA's RTA checklist
- Cross-check document formatting per eSTAR/eCopy specifications

Phase 5: Submission & Response Management

- Upload or ship complete eCopy/eSTAR to FDA with required cover materials
- Monitor status via FDA's Device Tracking system
- Be prepared to submit Additional Information (AI) responses within 180 days
- Track and document all FDA communications for internal reference
- Coordinate with legal/regulatory affairs in case of reclassification or queries

Phase 6: Commercialization Readiness

- Finalize labeling and marketing collateral per cleared indications
- List device in FDA's Device Registration & Listing database
- Archive 510(k) submission for internal audits and inspections
- Create training materials for sales, support, and clinical staff
- Set up Post-Market Surveillance (PMS) and customer feedback system