FDA Medical Device Approval Checklist
Class I, II & III Devices

STEP 1: DEVICE CLASSIFICATION

- Device class identified (I, II, or III)
- Product code, regulation number, and risk level confirmed
- Class exemptions reviewed for 510(k) or registration

STEP 2: REGULATORY PATHWAY SELECTION

- Substantial equivalence confirmed (510(k))
- No predicate exists → De Novo considered
- High-risk → PMA path selected
- Pre-Sub/Q-Sub meeting scheduled if needed

STEP 3: APPLICATION PREPARATION

- Device description and labeling completed
- Performance/bench testing finalized
- Biocompatibility, sterilization, software, clinical data (if needed) prepared
- Risk analysis and benefit-risk justifications included

STEP 4: SUBMISSION & REVIEW

- eCopy or eSTAR format used
- Submission tracking number received
- Deficiency letters responded to within deadline
- Final clearance or approval letter archived