

# FDA 510(k) Submission Readiness Checklist

Be Prepared. Submit with Confidence.

**01**

## Device & Regulatory Strategy

- ☐ Device description and intended use are clearly defined.
- ☐ Indications for use and proposed claims are documented.
- ☐ Device classification and applicable product code have been assessed.
- ☐ Applicable FDA pathway has been evaluated.
- ☐ Device risks and regulatory considerations have been identified.

**02**

## Predicate Device & Substantial Equivalence

- ☐ Potential predicate device(s) have been identified and reviewed.
- ☐ Predicate selection rationale is documented.
- ☐ Intended use comparison has been evaluated.
- ☐ Technological characteristics comparison has been completed.
- ☐ Differences between devices and their impact on safety or effectiveness have been assessed.

**03**

## Testing & Evidence Strategy

- ☐ Required performance testing has been identified.
- ☐ Applicable FDA guidance and recognized standards have been reviewed.
- ☐ Biocompatibility requirements have been assessed, where applicable.
- ☐ Electrical safety and EMC testing needs have been evaluated, where applicable.
- ☐ Software, cybersecurity, and usability considerations have been addressed, where applicable.
- ☐ Sterilization, shelf-life, or packaging requirements have been assessed, where applicable.
- ☐ Clinical evidence requirements have been evaluated, where applicable.

**04**

## 510(k) Submission Documentation

- ☐ Device description and technical specifications are complete.
- ☐ Indications for use statement is aligned with the device claims.
- ☐ Predicate comparison documentation is prepared.
- ☐ Testing reports and supporting evidence are available.
- ☐ Risk management documentation supports the submission strategy.
- ☐ Labeling and instructions for use are consistent with the submission.
- ☐ Submission sections are technically and regulatorily consistent.

**05**

## FDA Review Readiness

- ☐ Submission content has undergone regulatory review.
- ☐ Potential FDA questions and review risks have been assessed.
- ☐ Additional information response strategy is established.
- ☐ Supporting evidence can be traced to submission claims.
- ☐ Submission updates and revisions are controlled.

**06**

## Post-Submission & Lifecycle Considerations

- ☐ Change-control processes are established for future modifications.
- ☐ Regulatory impact assessment process is defined.
- ☐ Registration and listing obligations are understood, where applicable.
- ☐ Post-clearance regulatory responsibilities are planned.

