

FDA Regulatory Readiness Checklist

Assess. Prepare. Submit. Succeed in the U.S. Market.

Use this checklist to review key FDA regulatory considerations for your medical device.
Mark your current status and identify any gaps before you move forward.



A practical tool
to plan your
FDA journey.

01


Device & Intended Use

Key Considerations	Yes	Partial	No	N/A
Device definition and intended use are documented.	☐	☐	☐	☐
Indications, patient population and use environment are defined.	☐	☐	☐	☐
Claims are identified and supported by the proposed use.	☐	☐	☐	☐
Device configuration and technological characteristics are documented.	☐	☐	☐	☐

02


Classification & Pathway

Key Considerations	Yes	Partial	No	N/A
FDA classification has been assessed.	☐	☐	☐	☐
Applicable regulation and product code have been identified or investigated.	☐	☐	☐	☐
Potential 510(k), De Novo, PMA or other pathway has been assessed.	☐	☐	☐	☐
Predicate availability has been evaluated where relevant.	☐	☐	☐	☐

03


Evidence & Testing

Key Considerations	Yes	Partial	No	N/A
Required performance testing has been identified.	☐	☐	☐	☐
Risk-management considerations are documented.	☐	☐	☐	☐
Biocompatibility, EMC, electrical safety, sterilization or other testing has been assessed where applicable.	☐	☐	☐	☐
Clinical evidence requirements have been evaluated.	☐	☐	☐	☐
Software, cybersecurity and human-factors considerations have been assessed where applicable.	☐	☐	☐	☐

04


Submission Documentation

Key Considerations	Yes	Partial	No	N/A
Device description and specifications are complete.	☐	☐	☐	☐
Regulatory history and predicate information are documented where applicable.	☐	☐	☐	☐
Testing reports and supporting evidence are available.	☐	☐	☐	☐
Labeling and claims are aligned with the proposed submission.	☐	☐	☐	☐
Submission sections are internally consistent.	☐	☐	☐	☐

05


Quality & Establishment

Key Considerations	Yes	Partial	No	N/A
Applicable QMS requirements have been assessed.	☐	☐	☐	☐
Establishment registration and device listing requirements have been evaluated.	☐	☐	☐	☐
Manufacturer/importer responsibilities are understood.	☐	☐	☐	☐
U.S. Agent requirements have been assessed for foreign establishments.	☐	☐	☐	☐
Required quality records are available.	☐	☐	☐	☐

06


FDA Interaction & Review

Key Considerations	Yes	Partial	No	N/A
FDA questions and correspondence are tracked.	☐	☐	☐	☐
A process exists for reviewing and responding to FDA requests.	☐	☐	☐	☐
Additional-information responses are supported by objective evidence.	☐	☐	☐	☐
Submission changes and amendments are controlled.	☐	☐	☐	☐
Regulatory decisions are documented.	☐	☐	☐	☐

07


Post-Market & Lifecycle

Key Considerations	Yes	Partial	No	N/A
Change-control and regulatory impact assessment processes are established.	☐	☐	☐	☐
Applicable MDR/reporting obligations are understood.	☐	☐	☐	☐
Corrections and removals requirements have been assessed where applicable.	☐	☐	☐	☐
Registration and listing information can be maintained.	☐	☐	☐	☐
Post-clearance/post-approval regulatory activities are planned.	☐	☐	☐	☐



Identify gaps. Plan next steps.

Download the full checklist
and get started with your
FDA readiness assessment.



**Download the FDA
Regulatory Readiness Checklist**

