1. Submission Strategy & Device Classification

Confirm the regulatory foundation before teams build the dossier or eSTAR package.

CRITICAL GATE	Do not draft a submission until classification, intended use, and target market are documented.

#	Technical review item	Evidence / reviewer note	Status
1	Define the device, accessories, software functions, variants, and configurations in scope.		[ ] D [ ] G [ ] N/A
2	Document the intended use, indications for use, target users, use environment, and patient population.		[ ] D [ ] G [ ] N/A
3	Confirm the U.S. device classification and identify the applicable regulation number and product code.		[ ] D [ ] G [ ] N/A
4	Check whether exemptions, special controls, or device-specific guidance change the submission strategy.		[ ] D [ ] G [ ] N/A
5	Identify each target market and separate U.S. FDA requirements from EU MDR requirements.		[ ] D [ ] G [ ] N/A
6	Record the proposed marketing claims and verify that the evidence plan can support each claim.		[ ] D [ ] G [ ] N/A
7	Identify combination-product, IVD, software, cybersecurity, or human-factors considerations early.		[ ] D [ ] G [ ] N/A
8	Approve a written regulatory strategy with pathway, evidence, owners, milestones, and decision points.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA premarket submission selection and device classification framework.

2. Pathway Selection: 510(k), De Novo or PMA

Choose the FDA route using risk, novelty, predicate availability, and evidence expectations.

CRITICAL GATE	A wrong pathway decision can invalidate months of testing and documentation work.

#	Technical review item	Evidence / reviewer note	Status
1	For a 510(k), identify at least one legally marketed predicate with a defensible comparison strategy.		[ ] D [ ] G [ ] N/A
2	Confirm that differences from the predicate do not raise new questions of safety or effectiveness.		[ ] D [ ] G [ ] N/A
3	For De Novo, document why no legally marketed predicate supports a 510(k) approach.		[ ] D [ ] G [ ] N/A
4	For PMA, confirm Class III status and build the evidence plan around reasonable assurance requirements.		[ ] D [ ] G [ ] N/A
5	Check whether a Q-Submission or Pre-Submission meeting could reduce uncertainty before major testing.		[ ] D [ ] G [ ] N/A
6	Align the pathway decision with clinical, bench, software, biocompatibility, sterilization, and usability needs.		[ ] D [ ] G [ ] N/A
7	Document alternative pathways considered and explain why the selected route offers the strongest rationale.		[ ] D [ ] G [ ] N/A
8	Obtain cross-functional approval before locking protocols, sample sizes, and submission timelines.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA: 510(k), De Novo, PMA and other premarket submission types.

3. Predicate & Substantial Equivalence Review

Build a traceable 510(k) comparison that links technological differences to supporting evidence.

CRITICAL GATE	Do not rely on a predicate name alone; document intended use and technological comparisons.

#	Technical review item	Evidence / reviewer note	Status
1	Verify the predicate is legally marketed and appropriate for the proposed substantial-equivalence argument.		[ ] D [ ] G [ ] N/A
2	Compare intended use, indications, design, materials, energy source, software, and operating principles.		[ ] D [ ] G [ ] N/A
3	List every technological difference and assign evidence that addresses the resulting safety question.		[ ] D [ ] G [ ] N/A
4	Avoid unsupported statements such as “same” or “equivalent” without objective comparative evidence.		[ ] D [ ] G [ ] N/A
5	Ensure bench protocols use acceptance criteria linked to specifications, risk controls, or standards.		[ ] D [ ] G [ ] N/A
6	Confirm comparison tables use consistent terminology across labeling, testing, and device descriptions.		[ ] D [ ] G [ ] N/A
7	Check that test articles represent the final or justified production-equivalent device configuration.		[ ] D [ ] G [ ] N/A
8	Perform an independent reviewer challenge of the substantial-equivalence narrative before submission.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA 510(k) substantial-equivalence principles and product-specific guidance.

4. eSTAR & Administrative Submission Controls

Control the electronic package, required fields, attachments, and final submission version.

CRITICAL GATE	Most 510(k) and De Novo submissions require eSTAR unless an exemption applies.

#	Technical review item	Evidence / reviewer note	Status
1	Use the current FDA eSTAR version and confirm the correct submission type before data entry.		[ ] D [ ] G [ ] N/A
2	Complete every required eSTAR field and resolve validation messages before finalizing the package.		[ ] D [ ] G [ ] N/A
3	Use controlled attachment names that match the document index and internal document-control records.		[ ] D [ ] G [ ] N/A
4	Check that signatures, declarations, truthfulness statements, and contact information are current.		[ ] D [ ] G [ ] N/A
5	Verify all attachments open correctly and contain readable tables, figures, bookmarks, and searchable text.		[ ] D [ ] G [ ] N/A
6	Confirm the package contains the correct device description, labeling, testing, and administrative content.		[ ] D [ ] G [ ] N/A
7	Freeze the final submission version and archive the exact package sent to FDA.		[ ] D [ ] G [ ] N/A
8	Assign an owner to track acknowledgements, review communications, deficiencies, and response deadlines.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA eSTAR Program; mandatory use for most 510(k) and De Novo submissions.

5. Risk Management, Verification & Validation

Show that evidence addresses known hazards, design requirements, and intended-use conditions.

CRITICAL GATE	Every important risk control should connect to objective verification or validation evidence.

#	Technical review item	Evidence / reviewer note	Status
1	Maintain a current risk-management file that covers normal use, foreseeable misuse, and failure conditions.		[ ] D [ ] G [ ] N/A
2	Trace safety-related design inputs to implemented controls and objective verification evidence.		[ ] D [ ] G [ ] N/A
3	Confirm verification protocols define methods, sample rationale, acceptance criteria, and deviations.		[ ] D [ ] G [ ] N/A
4	Confirm validation uses production-equivalent devices and representative users or use conditions when needed.		[ ] D [ ] G [ ] N/A
5	Justify any untested requirement, waived test, reduced sample size, or protocol deviation.		[ ] D [ ] G [ ] N/A
6	Reconcile failed or marginal results with investigations, design changes, CAPA, and final conclusions.		[ ] D [ ] G [ ] N/A
7	Ensure software, cybersecurity, electrical safety, EMC, biocompatibility, and sterilization evidence is complete.		[ ] D [ ] G [ ] N/A
8	Complete a final traceability review from hazards and requirements through tests and submission claims.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: Risk-based evidence planning; applicable recognized standards and FDA guidance.

6. Clinical & Performance Evidence Readiness

Confirm that clinical and performance data answer the regulatory questions for the chosen pathway.

CRITICAL GATE	**Clinical evidence should support the exact intended use, population, claims, and residual risks.**

#	Technical review item	Evidence / reviewer note	Status
1	Define the clinical or performance questions that cannot be resolved through non-clinical evidence alone.		[ ] D [ ] G [ ] N/A
2	Confirm study populations, endpoints, comparators, follow-up, and statistical methods match regulatory goals.		[ ] D [ ] G [ ] N/A
3	Document protocol deviations, missing data, adverse events, and their impact on conclusions.		[ ] D [ ] G [ ] N/A
4	Align clinical claims in labeling with the strength and limitations of the submitted evidence.		[ ] D [ ] G [ ] N/A
5	Explain how literature, real-world data, or prior studies apply to the exact device configuration.		[ ] D [ ] G [ ] N/A
6	Assess whether device modifications affect the relevance of older clinical or performance evidence.		[ ] D [ ] G [ ] N/A
7	Ensure data tables, summaries, and source reports remain internally consistent across the submission.		[ ] D [ ] G [ ] N/A
8	Have medical, statistical, and regulatory reviewers approve the final benefit-risk interpretation.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA pathway-specific evidence expectations and EU MDR clinical evaluation principles.

7. Labeling, UDI & Human Factors

Make sure labeling communicates the reviewed device, claims, risks, and use conditions consistently.

CRITICAL GATE	A submission can fail when labeling makes claims that testing or clinical evidence does not support.

#	Technical review item	Evidence / reviewer note	Status
1	Keep intended use, indications, contraindications, warnings, and precautions consistent across documents.		[ ] D [ ] G [ ] N/A
2	Verify performance claims match the tested device, endpoints, acceptance criteria, and clinical conclusions.		[ ] D [ ] G [ ] N/A
3	Confirm instructions for use describe preparation, operation, cleaning, maintenance, and disposal as applicable.		[ ] D [ ] G [ ] N/A
4	Ensure critical tasks identified through use-related risk analysis receive adequate usability validation.		[ ] D [ ] G [ ] N/A
5	Resolve labeling changes created by design, software, packaging, sterilization, or risk-management updates.		[ ] D [ ] G [ ] N/A
6	Confirm UDI and device-identification information follows applicable market and device requirements.		[ ] D [ ] G [ ] N/A
7	Review symbols, units, terminology, translations, screenshots, and drawings for consistency and accuracy.		[ ] D [ ] G [ ] N/A
8	Run a final cross-document labeling comparison before the submission package is frozen.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA labeling and human-factors expectations; EU UDI/device information requirements.

8. QMSR, Manufacturing & Supplier Readiness

Connect the submission to a controlled quality system and a stable manufacturing process.

CRITICAL GATE	FDA QMSR became effective February 2, 2026 and incorporates ISO 13485:2016 by reference.

#	Technical review item	Evidence / reviewer note	Status
1	Confirm the quality system reflects current QMSR requirements and applicable ISO 13485:2016 controls.		[ ] D [ ] G [ ] N/A
2	Ensure design and development records support the device configuration described in the submission.		[ ] D [ ] G [ ] N/A
3	Verify manufacturing specifications, process controls, and acceptance activities match submitted evidence.		[ ] D [ ] G [ ] N/A
4	Qualify critical suppliers and document controls for outsourced processes, components, and test services.		[ ] D [ ] G [ ] N/A
5	Review process validation status for operations where output cannot be fully verified later.		[ ] D [ ] G [ ] N/A
6	Confirm complaint, nonconformity, CAPA, change, and risk processes can manage post-authorization issues.		[ ] D [ ] G [ ] N/A
7	Assess whether unresolved quality-system gaps could affect device safety, evidence credibility, or inspection readiness.		[ ] D [ ] G [ ] N/A
8	Document management approval for commercial manufacturing readiness before market launch.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: FDA Quality Management System Regulation (QMSR), effective February 2, 2026.

9. EU MDR & EUDAMED Readiness

Treat CE marking as a conformity-assessment route, not as an FDA-style premarket submission.

CRITICAL GATE	Since May 28, 2026, four EUDAMED modules are mandatory to use.

#	Technical review item	Evidence / reviewer note	Status
1	Confirm MDR device classification, applicable conformity-assessment route, and Notified Body involvement.		[ ] D [ ] G [ ] N/A
2	Maintain technical documentation that covers device description, GSPR evidence, risk, V&V, and labeling.		[ ] D [ ] G [ ] N/A
3	Ensure the clinical evaluation supports intended purpose, safety, performance, and benefit-risk conclusions.		[ ] D [ ] G [ ] N/A
4	Document post-market surveillance and PMCF planning that matches device risk and clinical uncertainties.		[ ] D [ ] G [ ] N/A
5	Confirm Actor registration and the Single Registration Number process where applicable.		[ ] D [ ] G [ ] N/A
6	Verify UDI/Device information is complete for required EUDAMED registration activities.		[ ] D [ ] G [ ] N/A
7	Check Notified Body certificate information and responsibilities for EUDAMED updates where applicable.		[ ] D [ ] G [ ] N/A
8	Track changes that could require technical-documentation updates, Notified Body review, or new registrations.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: EU MDR 2017/745 and European Commission EUDAMED mandatory-use information.

10. Final Submission QC & Go / No-Go Review

Run one controlled, cross-functional review before sending the dossier to a regulator or Notified Body.

CRITICAL GATE	Submit only when critical gaps are closed, documented, and approved by accountable functions.

#	Technical review item	Evidence / reviewer note	Status
1	Reconcile the device description, intended use, claims, specifications, labeling, and test configuration.		[ ] D [ ] G [ ] N/A
2	Confirm every required document is approved, current, readable, complete, and correctly referenced.		[ ] D [ ] G [ ] N/A
3	Close critical deviations, unresolved test failures, contradictory conclusions, and unexplained evidence gaps.		[ ] D [ ] G [ ] N/A
4	Verify hyperlinks, attachment names, document numbers, versions, dates, signatures, and cross-references.		[ ] D [ ] G [ ] N/A
5	Complete an independent regulatory quality review by someone outside the primary authoring team.		[ ] D [ ] G [ ] N/A
6	Create a response plan for regulator questions, deficiency letters, interactive review, and information requests.		[ ] D [ ] G [ ] N/A
7	Archive the final submitted package, approval records, source evidence, and submission correspondence.		[ ] D [ ] G [ ] N/A
8	Record the formal go / no-go decision, open risks, owners, deadlines, and management authorization.		[ ] D [ ] G [ ] N/A

Status: D = Done | G = Gap / action required | N/A = Not applicable

Reference focus: Final readiness review using current FDA and European Commission requirements.

Primary 2026 reference links

- FDA - Premarket Submissions: Selecting the Correct Submission
- FDA - eSTAR Program
- FDA - Quality Management System Regulation (QMSR)
- European Commission - EUDAMED Overview

Educational use only. Always confirm pathway-specific requirements and current guidance before submission.