



UNITED STATES MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the U.S. market

1 Confirm the FDA regulatory identity

Define intended use, users, technology, and claims. Identify the likely FDA product code, regulation number, device type, class, and whether a premarket submission is needed.



General medical device



Software / connected



Implant / sterile / active



2 Choose the U.S. market-entry route

CLASS I



Lowest risk

Many Class I devices are exempt from 510(k), but general controls and other requirements still apply.

CLASS II



Moderate risk

Most Class II devices require 510(k) clearance and compliance with applicable special controls.

DE NOVO



Novel low/mod.

Classification request for new low-to-moderate risk devices when no legally marketed predicate exists.

CLASS III



Highest risk

Most Class III devices require PMA and valid scientific evidence of safety and effectiveness.

3 Build the U.S. market-access infrastructure



FDA / CDRH framework

Confirm classification, pathway, and applicable device-specific controls.



U.S. agent & roles

Foreign establishments appoint a U.S. agent; clarify legal manufacturer, specification developer, contract manufacturer, importer, and relabeler roles.



Registration & listing

Required establishments register annually and list devices using FDA systems after clearance/approval when applicable.



QMSR + UDI readiness

QMSR became effective Feb. 2, 2026; prepare ISO 13485-aligned QMS, UDI/GUDID, and controls.



Importer / distribution setup

Align customs, labeling, complaint handling, and U.S. distribution responsibilities.

4 Build the evidence stack



Administrative

Classification rationale, submission forms, establishment role data, declarations, and records.



Quality / QMSR

Risk-based QMS, design and development, supplier controls, CAPA, complaint handling, and records.



Verification & validation

Bench, biocompatibility, sterilization, packaging, shelf life, electrical safety/EMC, software V&V as applicable.



Clinical / software / cyber

Clinical evidence proportional to risk; software lifecycle, human factors, AI/ cybersecurity expectations where applicable.



Labeling / UDI

21 CFR Part 801 labeling, indications, warnings, claims, UDI, and GUDID data as applicable.



RA TRAP TO AVOID

Do not assume device class alone tells you the route. In the U.S., predicate availability, novelty, intended use, and device characteristics can shift the path.



STRATEGIC INSIGHT

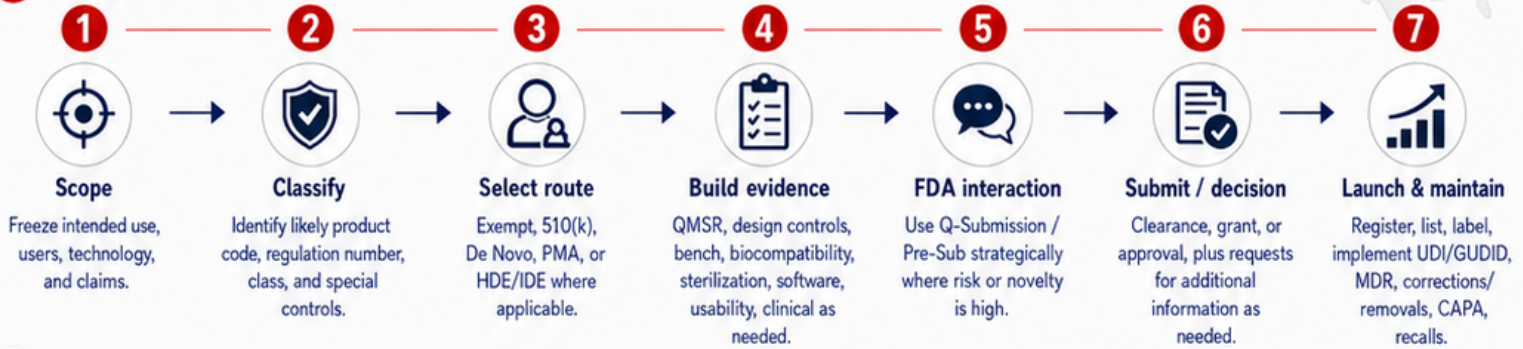
Start by freezing intended use, product code logic, and the likely predicate strategy. A strong pre-submission and evidence plan usually saves more time than rushing to file.



UNITED STATES MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — where the decision points a new RA professional should watch

A Program flow



B What gets heavier as risk and novelty rise?

Signal	CLASS I	CLASS II	DE NOVO	CLASS III
Premarket pathway	Often exempt	Usually 510(k)	Classification request	Usually PMA
Evidence intensity	● ● ● ● ● Lower	● ● ● ● ● Moderate	● ● ● ● ● Moderate-high	● ● ● ● ● Highest
Clinical / scientific support	● ● ● ● ● Not usually needed	● ● ● ● ● Sometimes limited clinical or usability depending on device	● ● ● ● ● May need more validation and sometimes clinical support	● ● ● ● ● Generally significant clinical evidence
Manufacturing / QMS readiness	● ● ● ● ● Basic	● ● ● ● ● Moderate	● ● ● ● ● High	● ● ● ● ● Very high
Post-market control	● ● ● ● ● Lower	● ● ● ● ● Moderate	● ● ● ● ● High	● ● ● ● ● Highest

C Indicative route-based planning ranges

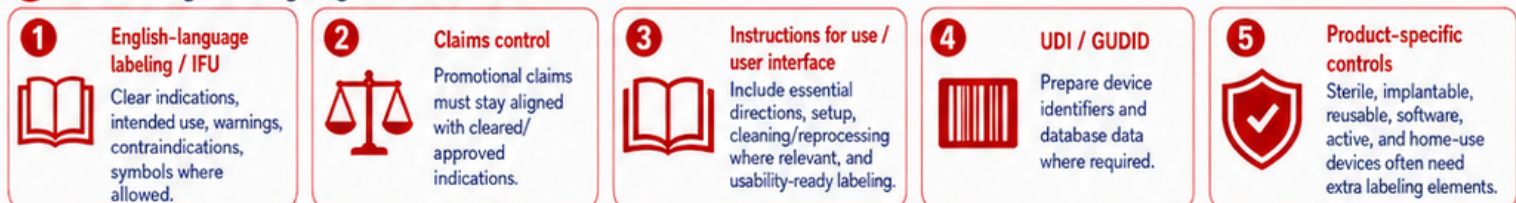


Pre-Sub use can reduce surprises when classification, testing, or clinical expectations are uncertain.



Total timing varies with product complexity, testing, software/cyber scope, clinical strategy, and FDA questions.

D Labeling & language essentials



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- [fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance)
- [fda.gov/medical-devices/premarket-notification-510k](https://www.fda.gov/medical-devices/premarket-notification-510k)
- [fda.gov/medical-devices/premarket-approval-pma](https://www.fda.gov/medical-devices/premarket-approval-pma)

- [fda.gov/medical-devices/de-novo-classification-request](https://www.fda.gov/medical-devices/de-novo-classification-request)
- [fda.gov/medical-devices/device-registration-and-listing](https://www.fda.gov/medical-devices/device-registration-and-listing)
- [fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr](https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr)



UNITED STATES MEDICAL DEVICE: EXECUTION DETAILS & HIGH-RISK ISSUES



Use this page to identify the issues most likely to change route, evidence burden, or launch timing.

E Country-specific decision points

1



Predicate strategy

A weak predicate strategy can derail a 510(k). Confirm product code, regulation, indications, technological characteristics, and special controls early.

2



De Novo vs PMA triggers

Novel intended use, no legally marketed predicate, or higher-risk technology can shift the plan from 510(k) to De Novo or PMA.

3



Device-type triggers

Sterile, reusable, implantable, active, electrically powered, MRI-related, home-use, or combination-related features often expand testing, labeling, and review complexity.

4



Software / cyber / AI

Connected software devices may need software lifecycle documentation, cybersecurity evidence, interoperability, human factors, and change-management discipline.

F Regulatory readiness checklist

- ☐ 1 Intended use and claims are frozen enough to classify reliably.
- ☐ 2 Product code, regulation number, class, and route rationale are documented.
- ☐ 3 U.S. agent, importer, relabeler, contract manufacturer, and legal manufacturer responsibilities are assigned as needed.
- ☐ 4 QMSR-aligned QMS and design-development controls are ready for the chosen route.
- ☐ 5 Verification and validation plan covers bench, biocompatibility, sterilization, packaging, electrical safety/EMC, software, cybersecurity, and usability as applicable.
- ☐ 6 Clinical evidence strategy is proportionate to risk, novelty, and device type.
- ☐ 7 Labeling, IFU, UDI, and promotional claims are launch-ready and route-aligned.
- ☐ 8 Registration, listing, complaint handling, MDR, CAPA, and recall/corrections-removals readiness are in place.

G Special FDA programs / non-routine paths



IDE — when clinical investigation of significant-risk devices is required



HDE — for devices intended to benefit patients with rare diseases or conditions



Breakthrough / STeP — expedited interaction programs for eligible devices



USE THE TIMELINES AS PLANNING RANGES, NOT REGULATORY PROMISES

Actual duration depends on product classification, predicate strategy, evidence maturity, testing scope, software/cyber complexity, clinical needs, FDA questions, manufacturing readiness, and postmarket infrastructure. Build a device-specific critical path before committing launch dates.



Accuracy review basis: current official FDA sources accessed August 2026.
Verify product-specific requirements at execution.