SDI ScienceDocs Inc.
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Regulatory Pathway Snapshot

A practical worksheet for early-stage teams to clarify the likely regulatory pathway, evidence expectations, decision points, and next actions before investing in development, pilots, funding applications, or commercialization planning.

How to use this snapshot

Use this tool as an early planning aid, not as legal or regulatory advice. Complete the sections with your team, mark assumptions clearly, and identify where agency guidance, regulatory counsel, quality expertise, clinical input, or reimbursement expertise is needed.

1. Product / Technology Overview

Field	Response
Product, platform, or technology name	
Brief description of the product or service	
Primary intended use or claim being considered	
Target users, customers, or care setting	
Technology type	☐ Medical device ☐ Diagnostic ☐ Digital health / software ☐ AI / ML tool ☐ Therapeutic ☐ Biologic ☐ Lab service ☐ Other: _____
Current development stage	☐ Concept ☐ Prototype ☐ Bench tested ☐ Pilot ready ☐ Clinical/field evidence started ☐ Commercial launch planning
Key commercialization decision this snapshot should inform	

2. Intended Use, Users, and Claims

Question	Working Answer	Confidence	Evidence / Source
What problem does the product address?		☐ High ☐ Med ☐ Low	
Who will use the product directly?		☐ High ☐ Med ☐ Low	
Who benefits from the product?		☐ High ☐ Med ☐ Low	
What decision, workflow, diagnosis, treatment, or operational action does it support?		☐ High ☐ Med ☐ Low	
What claims must be avoided until evidence or clearance is stronger?		☐ High ☐ Med ☐ Low	
What language should be used cautiously in marketing, grants, or investor materials?		☐ High ☐ Med ☐ Low	

3. Preliminary Regulatory Classification

Regulatory Dimension	Initial Selection / Notes	Unresolved Questions
Likely product category	☐ Medical device ☐ IVD/diagnostic ☐ SaMD/software ☐ AI/ML-enabled software ☐ Drug ☐ Biologic ☐ Combination product ☐ Non-regulated / wellness / operational support ☐ Unknown	
Likely risk level	☐ Low ☐ Moderate ☐ High ☐ Unknown	
Primary regulator or authority to investigate	☐ FDA ☐ CMS/CLIA ☐ FTC/consumer claims ☐ HIPAA/privacy/security ☐ State/local ☐ EU/MDR/IVDR ☐ Other: _____	
Comparable products or predicate examples		
Potential pathway to investigate	☐ 510(k) ☐ De Novo ☐ PMA ☐ EUA/special pathway ☐ LDT/CLIA-related ☐ Non-device enforcement discretion ☐ General wellness ☐ Other/unknown	
Reason classification may change		

4. Regulatory Readiness Checklist

Area	Readiness Item	Prompt / Evidence to Capture	Status	Notes / Owner
Intended Use	Intended use is written in plain, specific language.	Can a reviewer understand what the product does and does not do?	☐ Yes ☐ Partial ☐ No	
Claims	Commercial and scientific claims are separated.	Are grant, investor, and marketing claims realistic for the current evidence?	☐ Yes ☐ Partial ☐ No	
Users	User roles and use environment are defined.	Who operates it, who interprets results, and where is it used?	☐ Yes ☐ Partial ☐ No	
Risk	Potential harm scenarios are identified.	What happens if the product gives wrong, delayed, or unclear information?	☐ Yes ☐ Partial ☐ No	
Evidence	Evidence needs are mapped to each claim.	What bench, analytical, clinical, usability, or real-world evidence is needed?	☐ Yes ☐ Partial ☐ No	
Quality	Quality system needs are understood.	Are design controls, documentation, traceability, and change control needed?	☐ Yes ☐ Partial ☐ No	
Software / AI	Software or AI lifecycle risks are identified.	Are data drift, model updates, bias, cybersecurity, and human oversight addressed?	☐ Yes ☐ Partial ☐ No	
Privacy	Data privacy and security considerations are identified.	Will the product collect, store, transmit, or analyze protected/sensitive data?	☐ Yes ☐ Partial ☐ No	
Labeling	Early labeling, instructions, and user warnings are drafted.	What must users know to use the product safely and correctly?	☐ Yes ☐ Partial ☐ No	
Regulatory Input	Need for counsel, pre-submission, or agency input is assessed.	What question should be answered before major investment?	☐ Yes ☐ Partial ☐ No	

5. Evidence and Validation Snapshot

Evidence Category	Current Evidence	Evidence Needed Before Next Milestone	Priority
Technical / bench performance			☐ High ☐ Med ☐ Low
Analytical validation / accuracy			☐ High ☐ Med ☐ Low
Clinical or field relevance			☐ High ☐ Med ☐ Low
Usability / human factors			☐ High ☐ Med ☐ Low
Cybersecurity / privacy testing			☐ High ☐ Med ☐ Low
Manufacturing / reproducibility			☐ High ☐ Med ☐ Low
Real-world pilot or implementation evidence			☐ High ☐ Med ☐ Low

6. Pathway Decision Matrix

Possible Pathway	Why It May Fit	Why It May Not Fit / Risks	Next Evidence or Expert Input Needed
Non-regulated / operational tool			
General wellness or low-risk support tool			
510(k) or predicate-based pathway			

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Possible Pathway	Why It May Fit	Why It May Not Fit / Risks	Next Evidence or Expert Input Needed
De Novo pathway			
PMA or high-risk pathway			
CLIA / laboratory-developed testing pathway			
EU MDR / IVDR or international pathway			
Other pathway			

7. Key Regulatory Assumptions

Assumption	Why It Matters	Evidence Needed to Confirm	Owner	Due Date
Example: Product can be positioned as decision support rather than autonomous diagnosis.	Changes risk level, claims, validation needs, and review pathway.	Regulatory review of intended use, workflow, user oversight, and comparable products.		

8. Red Flags and Open Questions

Potential Red Flag	Applies?	Notes / Mitigation
The product could influence diagnosis, treatment, safety, or clinical decisions.	☐ Yes ☐ No ☐ Unsure	
Claims exceed current evidence.	☐ Yes ☐ No ☐ Unsure	
No clear predicate or comparable regulated product has been identified.	☐ Yes ☐ No ☐ Unsure	
The product uses AI/ML that may change over time or depend on biased/incomplete data.	☐ Yes ☐ No ☐ Unsure	
Protected health information, sensitive data, or institutional data will be used.	☐ Yes ☐ No ☐ Unsure	
Pilot users may interpret the tool as validated beyond its current stage.	☐ Yes ☐ No ☐ Unsure	
Regulatory, reimbursement, and commercial claims are not aligned.	☐ Yes ☐ No ☐ Unsure	

9. Next-Step Action Plan

Action Item	Purpose	Owner	Target Date	Status
Draft or refine intended use statement.	Clarify classification and claims.			☐ Not started ☐ In progress ☐ Complete
Identify comparable products, predicates, or guidance documents.	Support initial pathway assessment.			☐ Not started ☐ In progress ☐ Complete
Map evidence needs to each planned claim.	Prevent over-claiming and plan validation.			☐ Not started ☐ In progress ☐ Complete
Consult regulatory, quality, clinical, or reimbursement expert.	Resolve high-risk assumptions.			☐ Not started ☐ In progress ☐ Complete
Update commercialization, grant, investor, and pilot materials.	Align external messaging with regulatory reality.			☐ Not started ☐ In progress ☐ Complete

ScienceDocs support

Need help applying this tool? ScienceDocs supports commercialization, change management, AI adoption, grant strategy, regulatory writing, evidence planning, and operational optimization for research-driven teams and technology organizations.