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Medical Device Dev Process Checklist

Define User Needs & Intended Use

- Identify target users, intended medical purpose, indications, and use environment

Plan Design & Development

- Create strategy, roles, and timelines aligned with FDA and ISO 13485
- Implement ISO 13485

Apply Risk Management (ISO 14971)

- Identify and assess hazards, mitigate risks by implementing risk controls, and evaluate and document residual risk results

Develop & Document Design

- Translate user needs into design inputs and outputs with traceability

Verification & Validation (V&V)

- Verify outputs meet inputs and validate that the device meets user needs
- Include preclinical, clinical, and usability testing

Regulatory Submission

- Select correct pathway (510(k), De Novo, PMA, CE marking under EU MDR)
- Prepare technical file and submit to authorities

Manufacturing

- Validated processes, and supplier controls

Market Launch & Post-Market Surveillance

- Provide labeling and training
- Monitor performance and update risk reviews