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FDA Medical Device Recall Response Checklist

Classification Assessment

- Risk to patient safety evaluated
- Determining the appropriate recall classification (I, II, III)
- Medical device Correction vs removal identified
- Recall scope (devices, lots, countries) defined

Immediate Recall Actions

- Notify internal QA/RA leadership
- Prepare field safety notice or customer letter
- Document decision-making under 21 CFR Part 806
- Notify FDA within 10 working days if applicable

Documentation & Reporting

- Recall strategy and timeline defined
- Root cause and risk analysis performed
- CAPA documented and linked to recall
- Track all communications and verify the effectiveness of recall actions

Post-Recall Compliance

- Submit follow-up updates to FDA or Health Authorities
- Conduct final effectiveness verification
- File closure letter to FDA upon completion
- Evaluate QMS updates to prevent recurrence