Labeling Changes that more likely - require a New 510(k):
FDA Compliance Checklist

Check: Change Type

- Intended use or indications for use changed?
- New clinical claims, outcomes, or performance benefits added?
- Contraindications, warnings, precautions or adverse effects revised?
- Change in patient population, end-user or use environment?
- Changes made to align with new performance testing, validation data or clinical studies?
- Changes to labeling that suggest a new mode of operation or mechanism of action?

Does NOT Typically Require 510(k)

- Formatting, font, colour or visual layout updates only
- Grammar, punctuation or spelling corrections
- Language translation with no content change
- Removal of outdated trademarks, branding elements or logos
- Updates to contact details (e.g., manufacturer address) with no impact on regulatory responsibilities

Documentation Checklist

- Rationale for change documented in relevant change control records- Justification signed off by RA/QA leadership
- Updated risk management file evaluation performed against FDA's 510(k) decision-making guidance flowchart
- Verification and validation records, if any
- Labeling changes reviewed during management review or design control procedures

Strategic Considerations

- Is a pre-sub (Q-sub) required based on the nature of the change and the regulatory status of the device
- Are changes bundled with a broader device modification?
- Is the substantial equivalence likely to be affected?