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Technological Change Compliance Checklist

Identify the Modification

- Device software updated or new algorithm added
- Hardware or material modified (e.g., sensors, interfaces)
- Performance specifications changed (e.g.,accuracy, sensitivity, range)
- Connectivity or control systems updated

Determine Impact on Safety/Effectiveness

- Change alters device function or risk profile
- New user interface or workflow introduced
- Potential clinical impact or interpretation shifts

Evaluate Predicate & Regulatory Path

- Check the device classification based on the changes, if any, in the intended or indications for use.
- In case of 510(k), Substantial equivalence to an existing cleared device documented
- In case of class I device, limits of exemption should be re-evaluated
- Predicate remains applicable post-modification
- If no predicate exists → De Novo route considered

FDA Guidance Alignment

- Flowchart reviewed from 2017 FDA Guidance
- Special controls and labeling requirements reviewed
- Internal justification for change documented

Final Checks Before Proceeding

- Regulatory team aligned on applicable documentation
- Applicable V&V performed and data compared
- Labeling changes, if any, verified
- Applicable forms in the QMSR are triggered
- Quality objectives are met
- External documents are obtained and controlled through QMSR
- Pre-sub or Q-submission considered for clarity