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FDA Class II Medical Device Compliance & 510(k) Checklist

Device Classification

- Intended use aligns with Class II risk category
- Product does not fall under PMA (Class III) or exempt Class I
- FDA product code and regulation number identified

Predicate Analysis

- At least one predicate device identified
- Demonstration of Substantial equivalence in terms of intended use and technological characteristics
- Predicate fully documented with 510(k) number and comparison table outlining similarities and differences

510(k) Documentation

- Completion of Device description, IFU, and labeling
- Performance testing and bench/lab data are compiled
- Biocompatibility and electrical safety reports (if applicable)
- Software documentation (if applicable, per FDA guidance)
- Risk analysis and mitigation summary

Special Controls

- All FDA-identified special controls reviewed
- Clinical data generated (if required)
- Post-market controls like device tracking or adverse event reporting included

Submission Strategy

- Correct 510(k) type chosen (Traditional / Abbreviated / Special)
- Submission is formatted as per FDA eSTAR or eCopy guidelines
- Timeline and pre-submission (Q-sub) planning complete