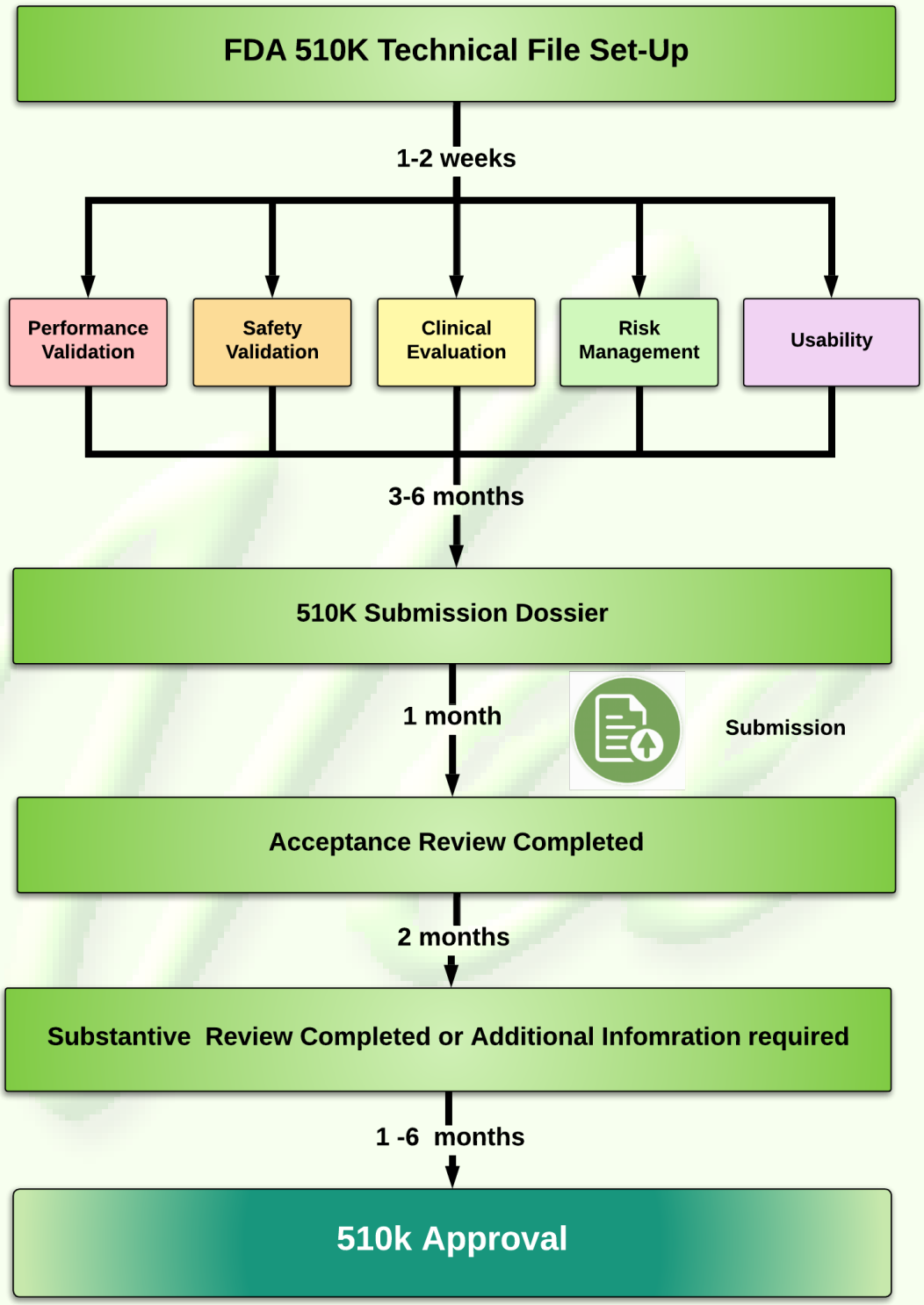
MARKET ACCESS TO US (510k)

REGISTRATION PROCESS



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DOCUMENTS REQUIRED

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- Indications for Use Statement
- 510(k) Summary or 510(k) Statement
- Truthful and Accuracy Statement
- DOC and Summary Reports
- Executive Summary
- Device Description
- Substantial Equivalence Discussion
- Proposed Labeling
- Risk Management
- Sterilization and Shelf Life
- Biocompatibility
- Software
- EMC and Electrical Safety
- Performance Testing - Bench
- Performance Testing - Animal
- Performance Testing – Clinical