Elexes

510(k) Submission Readiness Checklist

- Confirm device classification and 510(k) eligibility
- Identify and document a valid predicate device
- Define intended use and indications for use clearly
- Prepare a detailed device description and specifications
- Conduct all required performance and safety testing
- Complete biocompatibility and electrical safety assessments (if applicable)
- Perform sterilization validation and provide shelf-life data (if applicable)
- Develop software documentation and cybersecurity evidence (for software/SaMD)
- Conduct human factors and usability engineering studies (if applicable)
- Perform risk analysis aligned with ISO 14971
- Prepare clinical data or literature justification, where required
- Prepare labeling compliant with FDA requirements
- Compile a complete substantial equivalence comparison
- Verify FDA user fee payment and eCopy readiness
- Ensure post-market surveillance and complaint-handling readiness
- Conduct an internal regulatory review before submission