Elexes

De Novo Submission Checklist

REGULATORY PLANNING & STRATEGY

- Confirm no predicate device exists
- Justify Class I or II classification
- Prepare benefit-risk analysis per FDA guidance
- Plan and conduct a Pre-Sub meeting with the FDA
- Develop a De Novo-specific regulatory strategy

EVIDENCE & DOCUMENTATION

- Complete bench and performance testing
- Include biocompatibility, electrical, or software validation (if applicable)
- Include clinical data or rationale for exemption
- Prepare risk management file per ISO 14971
- Finalize device description, labeling, and IFU

DE NOVO REQUEST PREPARATION

- Format submission per eSTAR or eCopy guidelines
- Include proposed classification and special controls
- Designate US Agent (if applicable)
- Ensure all forms and attachments are complete
- Confirm readiness for FDA queries or Additional Information requests