

De Novo Submission Readiness Checklist

1. **Device Overview:** Clear description of the device, intended use, and technology.
2. **Predicate Analysis:** Evidence showing no legally marketed predicate exists.
3. **Risk Assessment:** Identification of risks and mitigation measures.
4. **Benefit–Risk Analysis:** Discussion demonstrating that probable benefits outweigh probable risks.
5. **Performance Testing:** Relevant bench, software, and safety testing data.
6. **Clinical Evidence (if applicable):** Summary of clinical data or justification if not required.
7. **Proposed Special Controls:** Suggested controls to ensure safety and effectiveness.
8. **Labeling:** Draft indications for use, instructions, warnings, and precautions.
9. Sterilization, biocompatibility, EMC, and shelf-life information when applicable.
10. **FDA Interactions:** Pre-Submission feedback and how it was addressed.