

Breakthrough Device Submission Checklist

Device and Clinical Justification

- Confirm the device addresses a life-threatening or irreversibly debilitating condition
- Demonstrate the device's potential for more effective treatment or diagnosis compared to existing options
- Provide information (bench, animal, and/or clinical, as appropriate) sufficient to show the device meets the statutory criteria

Submission Documentation

- Prepare a clear cover letter highlighting why the device meets breakthrough criteria
- Include a comprehensive device description and intended use
- Provide justification for how the device addresses unmet medical needs
- Summarize supporting data and references

Regulatory Alignment and Review

- Align submission format with the FDA's Breakthrough Device Designation guidance
- Ensure internal QA and regulatory team review before submission
- Plan for post-designation commitments and resource allocation