Elexes

510(k) Types Comparison Checklist – Traditional, Special & Abbreviated

510(k) Type Overview

Type	Review Time	Use Case	Key Requirement
Traditional	~90 days	Most common	Full performance and comparison data
Special	~30 days	Minor modification to cleared device	Clear linkage to previously cleared device, no new data needed
Abbreviated	~90 days	Guidance exists	Uses recognized consensus standards

Key Decision Points

- Is your device a modification of your previously cleared device? → Consider Special 510(k)
- Does FDA guidance or a recognized standard exist? → Consider Abbreviated 510(k)
- Are you relying on new performance data and a predicate? → Consider Traditional 510(k)
- Are changes only to labeling, indications, or design with no impact on safety or effectiveness? → Special 510(k) may be appropriate

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Submission Document Checklist (By Type)

Document Type	Traditional	Special	Abbreviated
Truthful & Accuracy	✅	✅	✅
Device Description	✅	✅	✅
Predicate Comparison Table	✅	✅	✅
Performance Testing	✅	❌ (not required)	Optional if using standards
Consensus Standards Declaration	❌	❌	✅
Labeling & IFU	✅	✅	✅