# Emergo Group - Quality Assurance and Regulatory Affairs

# FDA510k.com

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## Traditional, Special and Abbreviated 510k Submissions

The FDA has three types of 510(k) Premarket Notification applications:

1. Traditional 510(k) submission
2. **Abbreviated** 510(k) submission
3. Special 510(k) submission

**TRADITIONAL 510(k) submission**
Most companies must submit a traditional 510(k) Premarket Notification which is a full 510(k) that includes all of the sections shown below:

1. Medical Device User Fee Cover Sheet
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing ? Bench
19. Performance Testing ? Animal
20. Performance Testing ? Clinical
21. Other

**ABBREVIATED 510(k) submission**
However, there are some instances where a company might qualify to submit an Abbreviated 510(k) if:

- A guidance document exists
- A special control has been established, or
- The FDA has a recognized Consensus Standard

When you submit an Abbreviated 510(k), you are providing summary reports that demonstrate your use of guidance documents, special controls or Declarations of Conformity to recognized standards to expedite review of your submission.

**SPECIAL 510(k) submission**
The final type of FDA Premarket Notification is called the Special 510(k). This is used when a modification has been made to a medical device that already has 510(k) clearance. In this case, you may qualify to submit a Special 510(k) It allows the manufacturer to declare ocnformance with the Design Controls set out of 21 CFR Part 820 without providing the data. The special 510(k) also applies to Preamendment Devices (those approved before May 28, 1976).