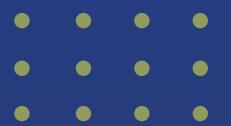




# 4 Smart Tips to Nail Your **FDA 510(k)** Submission

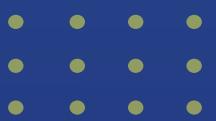


*Avoid delays.  
Get clearance faster.*



# Know Your Device Classification

*Not all devices need a **510(k)**.  
Start with the right classification to  
avoid wasting time and money.*





⋮  
⋮  
⋮  
⋮

## Find the Right Predicate Device

Your **510(k)** hinges on substantial equivalence. Pick a well-cleared predicate device to strengthen your submission.

⋮  
⋮  
⋮  
⋮

Check the **FDA** product code database first.

# Get Your **Documentation** in Order



*Technical file, testing data, labeling,  
IFU-don't leave anything out.*

**Incomplete submissions = FDA hold = Delay**

Keep a checklist.

Double check everything.

# Use FDA's eSTAR Template

*The FDA loves structure - and  
eSTAR gives you that.*

Streamlined  
Faster Reviews  
Fewer back-and-forths



Ready to **Submit**  
Your  
**510(k)** ?

*Avoid costly mistakes.  
Get expert help.*

*Contact us to start your  
FDA 510(k) submission the right way.*

