

The background of the entire page is a close-up, wavy image of the American flag, showing the stars and stripes in a dynamic, flowing manner.

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.*