

FDA 510(K) CLEARANCE PROCESS CHECKLIST

1. Confirm the **classification** of your medical device and whether it falls under the **510(k) pathway**.
Example: XXXXXX is a class II medical device
2. Using the FDA website, identify the appropriate **three-letter product code** and regulation number for your device.
Example: Product code LEL (Sleep Assessment Device)
Example: Regulation number: 882.5050 Biofeedback device
3. Conduct research on the **FDA database** and select a predicate for comparison.
Example: Substantially equivalent to the predicate device XXX cleared under YYY.
4. Search the FDA website for applicable FDA guidance documents. Examples include:
 - Guidance for the **content of premarket submission for software** contained in medical devices
 - Content of **premarket submissions for management of cybersecurity in medical devices** applying human factors and usability engineering to medical devices
 - Use of International Standard ISO 10993-1, "**Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process**"
5. Determine which **international “consensus standards”** may apply to your device by reviewing the 510(k) summary of the predicate device identified in item three above for the **standards** they may have used.
6. Identify clinical data and/or testing that may be required for your device by reviewing the 510(k) summary of the predicate device and testing they may have completed.
7. Complete performance testing and perform clinical studies (if required). Note that studies may need to comply with **Good Clinical Practice (GCP)** and **Good Laboratory Practice (GLP)**.
8. Assemble all **documentation** into the **510(k) submission**.
9. Review the **Refuse to Accept (RTA)** checklist to ensure that you are following the FDA guidelines for completeness.
10. Pay the 510(k) review fee, get the receipt, and then **submit the 510(k) to the FDA**.
11. Receive confirmation from FDA within two weeks that your 510(k) was accepted for substantive review.
 - Note that “substantive review” is an interactive process. FDA can send questions with short turn-around times for you to provide the information.
 - After 60 days of “substantive review” the FDA review team may put the 510(k) on “hold” and send a list of questions to address within 180 days.
 - If not completed within 180 days, 510(k) will be deleted, and a new 510(k) must be submitted, and a new fee will be charged.

12. If your 510(k) is determined to be substantially equivalent, you will receive a letter and it will be posted on the FDA website and this will serve as proof that your device may be legally marketed in the US. No certificate will be issued.

- Note that you will need to **register and list** the medical device after clearance is achieved.

The official nomenclature for a 510(k) is premarket notification. Note that FDA does not actually “approve” 510(k) submissions – they “clear” (authorize) a device to be marketed in the US. That’s why a 510(k) is called a premarket notification and not premarket approval (PMA), which applies only to Class III devices. The FDA does “approve” Class III medical devices via the PMA process.