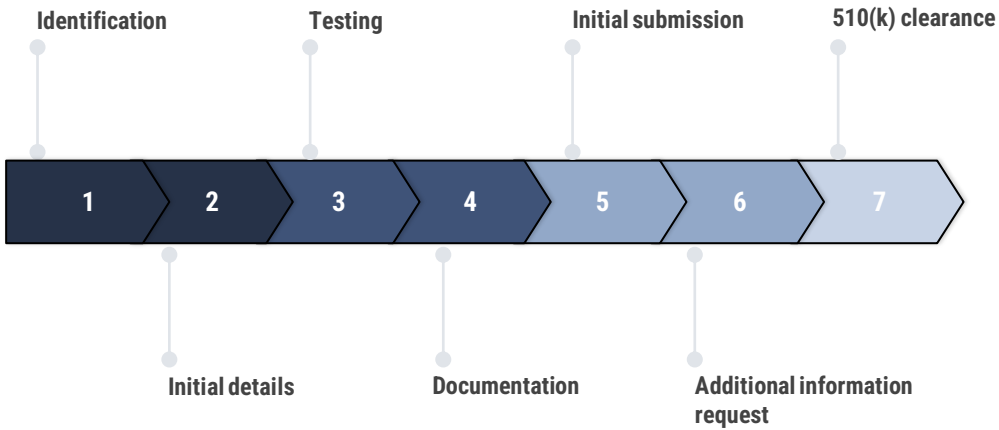
510(k) SUBMISSION STAGES

STAGES OVERVIEW



STAGE 1- IDENTIFICATION

- Classify the medical device and check if it requires 510(k)
- Identify the **product code** and **regulation number**
- Complete **establishment registration** and **device listing**

STAGE 2- INITIAL DETAILS

- Finalize **Indications for Use**
- Select **predicate device** to establish substantial equivalence
- Identify **clinical** and **non-clinical** tests required

STAGE 3- TESTING

Initiate testing as per applicable standards

- **Biocompatibility testing** to demonstrate safety
- **Performance testing** to prove effectiveness
- **Clinical testing** (if required)

STAGE 4- DOCUMENTATION

- Prepare **510(k) file**. For more details refer https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k
- Include **supporting information** like device drawing, manufacturing flowchart, test protocols and reports, labelling etc.

STAGE 5- SUBMISSION TO FDA

- Pay 510(k) review fee
- Submission of 510(k) file for substantive review

STAGE 6- ADDITIONAL INFORMATION

- FDA may request **additional information** (AI) after review by **day 60**.

AI response includes:

- Justification for questions raised by FDA
- Corrections made as per FDA suggestions

STAGE 7- 510(K) CLEARANCE

- If substantial **equivalence established**, **510(k) clearance** is granted by FDA

THANK YOU!

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