510(K) PRE-MARKET REVIEW PROCESS

Protecting American Patients and Promoting Medical Innovation

Before submission, **medical devices** are classified into three groups:

CLASS I	CLASS II	CLASS III
Pose a minimal risk to the user. Premarket submissions are typically not required.	Pose a moderate risk to the user and are important for healthcare. Premarket notifications are required.	Pose a high risk and include implanted medical devices or those that sustain life.

Day 1
FDA receives 510(k) submission.

By Day 7
FDA sends Acknowledgment Letter OR FDA sends Hold Letter if there are unresolved issues User Fee and/or eCopy.

By Day 15
FDA conducts Acceptance Review. FDA informs submitter if 510(k) is accepted for Substantive Review or placed on RTA Hold.

By Day 60
FDA conducts Substantive Review. FDA communicates via a Substantive Interaction to inform the submitter that the FDA will either proceed with review or that the 510(k) will be placed on hold and Additional Information is required.

By Day 90
FDA issues final Medical Device User Fee Act (MDUFA) Decision on 510(k).

By Day 100
If MDUFA Decision is not reached, FDA provides Missed MDUFA Decision Communication that identifies outstanding review issues.

Learn more at **ResponsibleAdsForPatientSafety.com**

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