AdvaMed
Advanced Medical Technology Association

The 510(k): Medical Device Approval

The FDA's 510(k) pre-market review process for medical devices provides strong protections to American patients and promotes medical innovation. It provides FDA the flexibility it needs to ensure the safety and effectiveness of low- and moderate-risk medical devices whose risks are well-understood from experience with similar devices.

The 510(k) review process provides for the thorough FDA review of a wide range of products – from syringes to imaging systems – in a timely fashion that facilitates patient access to needed medical advancements.

KEY DEFINITIONS:

510(k): A premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, or substantially equivalent, to a legally marketed device.

Pre-market approval: FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. This is a more involved process than 510(k).

Substantial equivalence to another legally U.S. marketed device: The new device is at least as safe and effective as the predicate. To note, the devices do not need to be identical. Substantial equivalence is established with respect to intended use, design, materials used, and other standards.

Medical devices are classified into three groups:

A. *Class I:* Pose a minimal risk to the user. Premarket submissions are typically not required.

B. *Class II:* Pose a moderate risk to the user and are important for health care. Premarket notifications are required.

C. *Class III:* Pose a high risk and include implanted medical devices or those that sustain life.

The process to receive 501(k) clearance typically takes 90 days from submission to clearance. The submitter may market the device immediately after 501(k) clearance is granted.

1. *Day 1:* FDA receives 510(k) submission.
2. *By Day 7:* FDA sends Acknowledgment Letter OR FDA sends Hold Letter if there are unresolved issues User Fee and/or eCopy.
3. *By Day 15:* FDA conducts Acceptance Review. FDA informs submitter if 510(k) is accepted for Substantive Review or placed on RTA Hold.
4. *By Day 60:* FDA conducts Substantive Review. FDA communicates via a Substantive Interaction to inform the submitter that the FDA will either proceed with Interactive Review or that the 510(k) will be placed on hold and Additional Information is required.
5. *By Day 90:* FDA sends final Medical Device User Fee Amendments (MDUFA) Decision on 510(k).
6. *By Day 100:* If MDUFA Decision is not reached, FDA provides Missed MDUFA Decision Communication that identifies outstanding review issues.