What is required for FDA device approval?

The level of regulation for medical devices is governed by the class to which a particular device is assigned by the FDA. Device classification is risk based, meaning that the user risk is a ***major*** factor in determining the class to which it is assigned. In addition, the device classification depends on the ***intended use*** (the exact use for which the product is intended) of the device as well as the ***indications for use*** (the precise reasons and situations as to why the product would be used).

Devices are assigned to the following classes:

- ***Class I*** includes devices with the lowest risk. Class I devices must meet "General Control" requirements in order to be released to market that include:
    - Suitability for intended use
    - Manufacture under a quality assurance program
    - Adequate packaging and labeling
    - Registration of the manufacturing site/establishment
    - Device listing
    - Good Manufacturing Practices (GMP)

- ***Class II*** includes devices of moderate risk. Devices in this class are not implantable. In addition to the General Control requirements from class I, class II devices must also meet the following special controls:
    - Performance standards
    - Postmarket surveillance requirements
    - Patient registry requirements
    - Special labeling requirements
    - Premarket data requirements
    - Guidelines

- ***Class III*** includes devices with the greatest risk. Devices in this class must meet all of the requirements in classes I and II. In addition, class III devices cannot be marketed until they receive Premarket Approval (PMA) or until a Premarket Notification (PMN) 510(k) submission is judged by the FDA to demonstrate "substantial equivalence" to a legally marketed device.

What is the difference between a PMA and a 510(k)?

The approval process for PMA devices is similar to that for prescription drugs, meaning that the **FDA requires the manufacturers of PMA devices to prove efficacy and safety by providing data showing the device's performance in humans (such as clinical trials).** The FDA also has the authority to regulate the promotion and marketing of PMA devices. As with prescription products, the manufacturers of PMA devices cannot make false or misleading claims about their devices; they also must include warnings and contraindications in any advertisement.

The manufacturers of 510(k) devices must demonstrate *only* that these devices have the same intended use and are substantially equivalent to similar legally marketed devices. The regulation of 510(k) devices is quite different. The FDA does not require human trials to prove efficacy and safety since these devices are considered to be at least as safe and effective as similar devices already on the market. **Instead, the manufacturers of 510(k) devices must demonstrate only that these devices have the same intended use and are substantially equivalent to similar legally marketed devices.**