The 510(k): Its Purpose, Compilation, and Submission

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Medical device companies must by law meet certain US Food and Drug Administration requirements before marketing a new or substantially modified (physically or in labeled/intended use) device in the US. Devices are generally defined. Devices may include associated components and software. Devices are classified based on risk to the patient. Classification determines the required level of control and submission requirements. Manufacturers must go through one of two evaluation processes: premarket notification (510[k]), unless exempt, or premarket approval (PMA), a much more involved...