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Sommario/riassunto	"The Food and Drug Administration (FDA) is responsible for ensuring that medical devices are safe and effective before they go on the

market. Section 510(k) of the Federal Food, Drug, and Cosmetic Act requires a manufacturer of medical devices to notify FDA of its intent to market a medical device at least 90 days in advance. That window of time allows FDA to evaluate whether the device is substantially equivalent to a product already legally on the market (called a predicate), in which case the device does not need to go through the premarket approval (PMA) process. As part of its assessment of the FDA's premarket clearance process for medical devices, the Institute of Medicine (IOM) held a workshop on July 28, 2010 to discuss how medical devices are monitored for safety after they are available to consumers. Its primary focus was on monitoring the safety of marketed medical devices, including FDA's postmarket surveillance activities, analysis of safety concerns that resulted in medical device recalls, and non-FDA sources of adverse-event information. Public Health Effectiveness of the FDA 501(K) Clearance Process summarizes the views of the workshop participants."--Publisher's description.
