



Public Health Effectiveness of the FDA 510(k) Clearance Process:: Balancing Patient Safety and Innovation: Workshop Report

*Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process, Board on Population
Health and Public Health Practice, Institute of Medicine*

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The Food and Drug Administration (FDA) is responsible for assuring that medical devices are safe and effective before they go on the market. As part of its assessment of FDA's premarket clearance process for medical devices, the IOM held a workshop June 14-15 to discuss how to best balance patient safety and technological innovation. This document summarizes the workshop.

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