

FROM PUBLIC CITIZEN:

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**Public Citizen Applauds IOM's Findings and
Recommendations on 510(k) Medical Device Clearance Process**
*Statement of Dr. Michael Carome, Deputy Director, Public Citizen's Health
Research Group*

Today, the Institute of Medicine's Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process issued a critically important report concluding that the Food and Drug Administration's (FDA's) 510(k) process for clearing medical devices is broken and cannot be fixed. In particular, the committee found that the legal standard used by the FDA for clearance of medical devices under the 510(k) process fails to ensure that devices are safe and effective.

The committee went on to recommend that the current FDA 510(k) clearance process "be replaced with an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle."

The FDA should accept the IOM's recommendations, abandon efforts to salvage the 510(k) process that are doomed to fail, and quickly move forward with developing and implementing a new, more robust regulatory framework for clearing medical devices that will protect the public health.

Public Citizen's Health Research Group for years has asserted that the FDA's procedures for clearing medical devices under the 510(k) process are flawed and fail to adequately protect public health. The FDA's prompt implementation of the IOM's recommendation will help ensure that the health of millions of patients who are treated with medical devices each year is not jeopardized.

To see more of Public Citizen's work critiquing the 510(k) clearance process, which was published in a medical journal article, visit: <http://www.citizen.org/hrg1912>.

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