

Use of recalled devices in new device authorizations under the US Food and Drug Administration's 510(k) pathway and risk of subsequent recalls.

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<https://psnet.ahrq.gov/issue/use-recalled-devices-new-device-authorizations-under-us-food-and-drug-administrations-510k>

The Food and Drug Administration (FDA) plays an [important role](#) in ensuring the [safety](#) of medical devices. In this cross-sectional study, researchers identified a high risk of future Class 1 FDA recall (the most serious recall designation, indicating serious risks to patient safety) among [previously authorized devices](#) (predicates) with prior Class 1 recalls.