Research Note

Do Predicate Device Recalls Signal Recalls of 510(k) Cleared Devices?

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The 510(k) process is used for many new medical devices to gain FDA clearance for marketing. The key requirement of 510(k) is that a new device be substantially equivalent to a 'predicate' device already cleared for sale. Later, 510(k)-cleared devices can serve as a predicate for other new devices, setting up a 'daisy chain' that can expedite and simplify entry of similar products into market. A Class I device recall is an FDA-mandated or manufacturer-elected removal of a device from market over concern of a 'reasonable probability of causing serious adverse health consequences or death.' Devices subject to mandatory Class I recalls can't serve as predicates. Controversially, devices voluntarily recalled by their manufacturers may serve as predicates, even if the predicate is in ongoing recall at the time of submission of a new 510(k).

A report in JAMA this month asked whether a voluntary Class I recall in a predicate device increases risk of a Class I or II recall in downstream 510(k) cleared product. This is important, especially for early-stage companies in high-patient-risk verticals like cardiovascular, neurosurgical and critical care. For large device companies, a Class I recall is a serious problem, but for start-ups betting everything on a single device, a Class I recall can easily end the company. *A predicate recall may be an investment warning sign.*

The authors examined 35,176 devices receiving 510(k) clearance between 2003 and 2018. Of these, 278 experienced at least one Class I recall (0.8%) and 4,117 had at least one Class II recall (11.7%). 133 (0.4%) 510(k) clearances referred to a Class I-recalled predicate. The impact of a predicate recall varied by device category, as shown in the figure below. Ortho, Cards, and Radiology historically see the most frequent recalls. In all 3 verticals, Class I events in predicate devices were an important predictor of product difficulty. When 1 or more recalls were present in a predicate, a device could expect a material increase in the risk of recall.

Bottom Line: Recalls among 510(k) cleared devices are uncommon, and Class I recalls are rare. Risk is significantly increased when a predicate device has a history of Class I recall. **Diligence of start-up devices with, or planning, 510(k) clearance should include some consideration of the track record of their predicate devices.**