FDA proposes new 510(k) pre-review to cut out incomplete applications

Mass Device

The FDA revises its 510(k) application policy and issues a new basic administrative checklist to pre-assess submissions for a certain level of completeness before passing them on for agency review.

The FDA issued new recommendations for improving the 510(k) medical device review process by installing a pre-review assessment that would check applications and reject submissions dubbed incomplete.

The proposal is one of the FDA's attempts to make good on the promises it made to the medical device industry in the latest iteration of the Medical Device User Fee & Modernization Act. The federal watchdog agency vowed to streamline its application review process in exchange for a doubling of fees that companies pay when submitting for review.