FDA's medtech review Plan of Action cuts review times, lowers application backlog

Mass Device

The FDA touts the success of its 36-point "Plan of Action" for streamlining the medical device premarket review process, noting improvements in predictability in transparency for the 1st time in nearly a decade.

The FDA's 36-point "Plan of Action" for improving its medical device review program produced success in turning around a process that had been worsening for nearly a decade, according to the federal watchdog agency.

The FDA reported that it "successfully increased the predictability, consistency, transparency, efficiency, and timeliness of premarket review," thanks to a 2-year initiative that included efforts to better manage agency resources, remove unnecessary regulatory burdens and bring in outside experts to streamline medical device review.

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