FDA approved almost all medical devices in the last year

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The Food and Drug Administration says it approved 98 percent of all high-risk medical devices submitted during the most recent fiscal year, the highest rate in at least 15 years.

The list includes heart valves, cancer tests, gastric balloons, spinal implants and other devices used by doctors and hospitals around the country.

The 98 percent approval rate compares to 86 percent last year and 70 percent in 2012, according to recent FDA figures. It's the highest level since at least 2001 and the first time the approval rate was in the 90s since 2005, when it was 90 percent.

For the medical-device industry, the approvals could translate into billions of dollars worth of new revenue and profits.

The higher numbers come as the FDA is facing the prospect of reform legislation in Congress based on the criticism that the agency's approval process is too slow and unresponsive, according to an analysis by PricewaterhouseCoopers.

"The approval percentages could help regulators combat that narrative," the consulting firm said in a recent report.

The devices were submitted through the FDA's "premarket approval" pathway, which is used to approve the riskiest type of medical devices,

such as replacement heart valves. The process requires the FDA to give more and earlier feedback about problems that might cause an application to be rejected.

Lower-risk devices are benefiting as well from FDA decisions. The agency approved 85 percent of all lower-risk devices in fiscal 2015, its highest approval percentage since 2010.

Some of the products approved were a bone graft made by BioMimetic Therapeutics in Tennessee and an insulin pump made by Tandem Diabetes Care in California, as well as a stent system made by Abbott Laboratories and a change in the syringe plunger tip material for Baxter International.