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## FDA to IOM: More work? No thanks

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The FDA is moving cautiously on a call by the Institute of Medicine to scrap the approvals process for many medical devices.

An IOM [report](#), released at the end of July, calls for a total rethink of the agency's 510(k) process, by which the similarity of "moderate risk" premarket devices like artificial hips to approved devices is assessed, but not their safety or efficacy. The device industry, unsurprisingly, disagreed strongly, with trade group AdvaMed, in what *The New York Times* called "an unusual preemptive strike," [saying](#) the report "does not deserve serious consideration from the Congress or the Administration. It proposes abandoning efforts to address the serious problems with the administration of the current program by replacing it at some unknown date with an untried, unproven and unspecified new legal structure. This would be a disservice to patients and the public health."

FDA's response was muted. The agency, which commissioned the report in 2009, opened a 30-day public comment period on the matter and issued a [statement](#) in which CDRH director Jeffrey Shuren said: "FDA believes that the 510(k) process should not be eliminated but we are open to additional proposals and approaches for continued improvement of our device review programs." Some of the changes advocated by the IOM, the agency noted, would require Congressional action.

The device industry has plenty of powerful political allies in both parties that the FDA may be wary of crossing. Just weeks after a nasty partisan shutdown of state government in Minnesota, a bipartisan swath of the state's congressional delegation issued a [joint statement](#) on the report, with Senator Al Franken saying "calling for the elimination of the 510(k) process could be very harmful to innovation. The report's recommendations would impose new burdens on the medical device industry, without a clear path to a more effective process. And in the meantime, it would leave Minnesota companies with great uncertainty, and patients without new lifesaving devices."

Plus, at a time of increasing austerity, agency leadership probably isn't eager to heap more responsibilities on their plate.

"Cynics would say it will wind up like most Washington reports – collecting dust on a shelf," says Wayne Pine of APCO Worldwide. "With the budget limits, there has to be an abbreviated process for many or most devices."

Proponents of a root-and-branch approach argue that consumers have a right to expect the same rigorous review of safety and efficacy applied to drugs of the devices they use.

"As a matter of law and logic and science, the report makes a lot of sense," says food and drug law expert Arnie

Friede. "It's not a safety or effectiveness review and if we want that in our regulatory regime, the 510(k) process ain't it. The IOM basically said this thing is so broken it can't be fixed, and it's a largely accurate assessment of the shortcomings of the process."

The Washington Legal Foundation filed a petition charging that the IOM committee was unfairly balanced and arguing that FDA was therefore legally mandated to ignore the report. Chief counsel Richard Samp said the IOM failed to make the case that the process has compromised public safety.

"Their essential complaint is with what I consider to be 510(k)'s principal asset, which is that it doesn't require a lengthy delay to prove safety and efficacy," said Samp. "We're not talking Class III devices, we're talking about devices that by definition don't raise life-threatening issues if you have some defect. I don't think they made the case that the tradeoff is worth it if you're going to slow down the process."