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QUOTED. April 12, 2019. Anonymous.

by

The US FDA wants to put a list online of devices using predicates more than a decade old as a way to discourage the use of older predicates, which may rely on outdated science. Device-makers are balking, while others – like one anonymous artificial hip patient – want even more action. See what that person said here.

“The FDA needs to shut down the entire 510(k) process, or get a handle on the biggest violators and culprits who are abusing the system for financial gain only. After three revisions, two dislocations and one ‘infection,’ I am pretty certain that something went way south here.” – [Anonymous](#) Artificial Hip Patient

- Find out more: [Industry Gets Extra Month For 510\(k\) Revamp Comments](#)

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