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QUOTED. Dec. 28, 2017. Jeff Shuren.

by

Check out what Jeff Shuren, director of US FDA's device center, has to say about a new proposed program from the agency that looks to streamline the Medical Device Reporting (MDR) process through the use of summary adverse event reports.

"While manufacturers must report certain device malfunctions to the FDA, these individual reports often describe the same problem, creating a process where the FDA conducts duplicate reviews of common malfunctions. We're proposing to streamline this process through a summary reporting system that would enable us to more efficiently detect potential safety issues and free up agency resources to better focus on addressing them." – Jeff Shuren, director, US FDA Center for Devices and Radiological Health

> Find out more: *FDA Asks For More Summary Adverse Event Reports Under Proposed MDR Program*

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