

19 Dec 2017 | Interviews

QUOTED. Dec 19, 2017. Jeff Shuren.

by

Check out what US FDA device-center director Jeff Shuren had to say about an alternative 510(k) pathway the center is developing that does not depend on a technology comparison to a predicate device.

"You can really say, this isn't your grandmother's device and it isn't your grandmother's standard." – Jeff Shuren, director, US FDA Center for Devices and Radiological Health

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