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QUOTED. 24 June 2019. Jeff Shuren.

by

The US FDA officially shuttered its Alternative Summary Reporting (ASR) Program on 21 June and released to the public millions of adverse event reports received by the agency between 1999 and 2019. See what the agency's device center chief, Jeff Shuren, said about it here.

"To formally end the program, we've issued revocation letters to the remaining 13 manufacturers with ASR exemptions, which covered ... dental implants, implantable cardiac defibrillators and pacemaker electrodes." – Jeff Shuren, director, FDA's Center for Devices and Radiological Health

- Find out more: *FDA Ends Summary Reporting Program, Releases 20 Years Of Adverse Events, Vows To Make MAUDE 'User-Friendly'*