

11 Nov 2021 | Analysis

Device Week, 11 November 2021 – Long-Awaited Software Guidance Released; FDA Panel Talks Stent Safety

by [Shawn M. Schmitt](#)

On this week's podcast: The US FDA finally issued a draft guidance for medical software in the premarket space, while an agency panel meeting focused on the safety of graft stents.

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Medtech Insight articles addressing topics discussed in this episode:

- [FDA's SaMD/SiMD Guidance Could Mean Documentation Headaches For Some Software Makers, Attorney Says](#)
- [Bleeding Risks Still A Concern For Patients With Endologix Stent Grafts: FDA Advisory Panel](#)