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Device Week, 27 September 2019 – Guidance, Guidance Everywhere...

by [Shawn M. Schmitt](#)

The US FDA has been furiously releasing a boatload of updated, draft and new guidance documents over the past month. On this week's podcast, we discuss three of them, related to clinical decision support (CDS) software, Humanitarian Use Devices (HUD) and Humanitarian Device Exemption (HDE).

Listen to the podcast via the player below:

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Medtech Insight articles addressing topics discussed in this episode:

- [*Industry Optimistic About Second CDS Draft Guidance; FDA Releases More Final Software Guidances*](#)
- [*New FDA Guidance Expands HUD Patient Limit*](#)
- [*Final Guidance Clarifies HDE Process, 'Probable Benefit'*](#)