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# Speaking Of Medtech, Ep. 2 – Breakthrough Medical Devices

by [Steve Silverman](#)

On this episode of our new podcast series Speaking Of Medtech, former US FDA device center compliance chief Steve Silverman and *Medtech Insight* executive editor Shawn M. Schmitt talk about the agency's Breakthrough Devices Program – what it is, how it operates, how device makers can take full advantage of the pathway, and more.

Listen to the podcast via the player below:

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*Medtech Insight* articles addressing topics discussed in this episode:

- [\*A 'STeP' Backward? Expert Predicts 'Slow, Quiet Death' For FDA's STeP Novel Devices Program\*](#)
- [\*Breathing Easy: ALung CEO Talks Novel Hemolung Device, FDA's Breakthrough Pathway, Landmark US/UK Clinical Trials\*](#)
- [\*'STeP' By 'STeP': FDA Finalizes Accelerated Pathway For Novel Devices, Combo Products\*](#)
- [\*US Breakthrough Devices Tracker\*](#)