## MEDTECH INSIGHT

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## QUOTED. Dec. 14, 2018. Aaron Josephson.

by

A revised bill circulating in both the US House and Senate would revamp FDA regulation of diagnostics to create a pre-certification process to validate test developers.

"Two key features of the bill that are likely to appeal most to diagnostic companies are precertification and review by accredited persons (i.e., third party review), both of which have to the potential to minimize FDA review, which is considered by some to be burdensome," - Aaron Josephson, Senior Director, ML Strategies

• Find out more: 'Reined-In' US Diagnostics Legislation Adds Pre-Certification, Other Updates

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