MEDTECH INSIGHT
CITELINE COMMERCIAL

14 Dec 2018 | **Analysis**

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 pre-certification 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*

Click here for a free trial of *Medtech Insight*