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QUOTED. 3 June 2019. US FDA.

by

An expert panel recommended the US Food and Drug Administration down-classify certain absorbable collagen hemostatic devices despite concerns there isn't enough clinical data to support their safety and efficacy. See what the agency said in a briefing document [here](#).

"In accordance with the 6-year rule, FDA considered data contained in two original PMAs approved for absorbable collagen-based hemostatic devices six or more years before the date of this panel to support our proposed classification recommendation." –US Food & Drug Administration

- Find out more: [Experts Recommend Down-Classifying Absorbable Collagen Hemostatic Devices Despite Data Doubts](#)

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